

## **AUSFTA CONFERENCE**

### **Health Impacts**

**Mr Philip Davies, Deputy Secretary, Department of Health and Ageing**

**1 - 2 March 2004**

#### **INTRODUCTION**

Thank you for inviting the Australian Government's Department of Health and Ageing to speak and contribute to the conference today.

The Department welcomes this opportunity to elaborate on and discuss the health impacts of the Australia United States Free Trade Agreement (the Agreement).

There has been much debate about the potential impacts of this Agreement on important and sensitive areas of the health system.

However the Government made it clear from the outset and throughout the negotiations that it would not allow the Agreement to compromise its capacity to deliver key objectives in health and other domestic policy areas.

The Government has delivered on that commitment – nothing has been agreed that undermines the fundamentals of the health system.

The US took a very tough line on some sensitive issues for Australia and I was struck by how hard negotiators worked right through to the end to uphold Australia's position that some areas – such as the fundamental architecture of the PBS – would not be negotiated away.

There are specific provisions in the Agreement relating to the Pharmaceutical Benefits Scheme, pharmaceutical intellectual property, plasma fractionation arrangements and professional services

- I welcome this opportunity to clarify what has been discussed and agreed concerning these issues

There has also been a lot of speculation that the Agreement will weaken the ability of governments to regulate for public purposes, including in relation to areas such as health

- That is not the case

I can also assure you that the Agreement has explicit exemptions for services supplied in the exercise of governmental authority, and for measures to protect human health and safety.

Nor does the Agreement prevent governments from owning public enterprises or maintaining a monopoly in the funding or provision of specific services.

The obligations in an FTA on services and investment govern the treatment afforded to foreign companies in comparison to local businesses, rather than limiting government's regulatory activity.

## **PHARMACEUTICAL BENEFITS SCHEME (PBS)**

So, what does the Agreement mean for the PBS?

- The Agreement will have *no effect* on the price of medicines or the policies that guide the selection of medicines for subsidy on the PBS

- There is nothing in the Agreement that will lead to any increases in the price of medicines on the PBS or increases in the costs to the Australian taxpayer.
- Under the Agreement Australia has agreed to some improvements in process and transparency in relation to the PBS
- All changes are process related.
- There are some clear benefits for Australia in what has been agreed in relation to the PBS in the Agreement. The agreed changes to the transparency and timeliness of PBS processes will be of benefit to consumers and industry alike.
- Issues relating to the PBS are covered by a Pharmaceuticals Annex to the Chapter in the Agreement on National Treatment and Market Access for Goods.
  - This Annex of the Agreement contains text that reflects some joint obligations and principles shared by Australia and the US in relation to health policy.
- There is also an exchange of letters on pharmaceuticals that sets out some specific commitments that Australia has made in relation to the processes by which new products are added to the list of medicines subsidised under the PBS.

### **Common principles**

- The Pharmaceuticals Annex sets out some common principles and objectives that Australia and the United States have agreed are important in managing their respective federal healthcare programs. The two countries recognise:

- the importance of government support for pharmaceutical research and development - including patent protection;
  - the importance of innovative products in delivering quality health care;
  - the need to promote efficient and transparent processes for the public to gain access to those innovative products; and
  - the need to ensure that those processes recognise the health benefits of innovative products.
- It's important to understand that these are statements of general principles only and don't require Australia to make any changes to the PBS.

### **Transparency and Process**

- The Annex also contains some general undertakings in relation to transparency and process that will apply to aspects of both countries' healthcare programs.
  - In practice, for Australia, most of the provisions of this part of the text reflect standards and practices that already apply when the Pharmaceutical Benefits Advisory Committee (PBAC) considers applications for new medicines to be added to the PBS.
  - These are such things as:
    - ensuring that applications from companies seeking to have products added to the PBS are considered by the PBAC within a specified timeframe;
    - publishing the procedural rules and guiding principles that govern the PBAC's consideration of those applications;
    - providing applicants with opportunities to comment to the PBAC during the process; and

- providing applicants with detailed explanations of the PBAC's consideration of their application.
- These, as I said, are all commitments that reflect our current practice.
- In addition there are also some new obligations contained in this part of the Annex.
  - The first is that more detailed information about the outcomes of the process will be made available to the public.
  - This, in my view, is an important step forward in transparency for both the Government and the pharmaceutical industry.
- For Australians this will mean an opportunity to gain a better understanding of the process by which medicines are added to the PBS and the reasons why some medicines are recommended by the PBAC and others are not. It is, after all, we Australians who pay for, and benefit from, the PBS so it is surely right that we can be provided with better insights into how it operates?
- Much has been made of the other key transparency provision of this Annex, the establishment of a review mechanism for PBAC outcomes.
  - In practical terms this will mean that a review mechanism will be provided but only in cases where PBAC recommends that a drug not be added to the PBS.
  - I can assure you that this process *will not* have the authority to overturn a recommendation of the PBAC and the PBAC will remain the “gate-keeper” to the PBS
  - Currently the Minister for Health and Ageing is bound by law to take advice from the PBAC and cannot list a medicine on the PBS that has not been recommended by the PBAC.
  - *This will not change with the introduction of this review mechanism.*

- The details of how the review process will operate are yet to be worked out, but stakeholders will be consulted as part of the process.

## **Exchange of Letters**

- As I mentioned earlier, a related Exchange of Letters on pharmaceuticals contains some additional process and transparency provisions
  - Here again, much of the text reflects current practice:-
    - by providing applicants to PBAC with an opportunity to discuss their application with technical staff of the Department of Health and Ageing prior to lodging it;
    - by allowing them to respond to any reports or evaluations concerning their application; and
    - by giving them timely information about the reasons for the outcome of that application
- In addition, Australia has agreed to provide applicants with an opportunity for a hearing before the PBAC while it is considering applications.
  - currently the PBAC considers applications on the basis of an exchange of papers only.
- Australia has also agreed to streamline some of the administrative steps that are required before a drug is added to the PBS. This will save time by:
  - reducing the time between the PBAC's recommendation and the medicine being available on the PBS;
  - revising and distributing the Schedule of Pharmaceutical Benefits (the "Yellow Book") more frequently.
- This will be of benefit both to industry and to consumers by providing faster access to subsidies for new prescription medicines.

## **Closer cooperation**

- Australia and the United States have also agreed to establish a Medicines Working Group as a forum for further discussion of the issues covered by the Annex.
  - It will be similar to other Working Groups that will be set up to discuss other aspects of the Agreement.
  - The Working Group will be made up of government officials only - it will not be a stakeholder forum or an opportunity for the pharmaceutical industry to lobby government on issues such as pricing.
- The details of how the Working Group will operate and the frequency of meetings is yet to be decided but it will offer additional useful opportunities for Australia to keep abreast of emerging issues in both domestic and international pharmaceutical markets.
- There is also a provision promoting closer cooperation between the Therapeutic Goods Administration (TGA) and the US Food and Drug Administration (FDA).
  - This will serve to strengthen the existing relationship between these two organisations.
  - However it does not mean that the TGA will be required to accept products that the FDA approves, or vice versa.

## **Dissemination of information**

- There was a great deal of speculation that the USFTA might have required Australia to make concessions in the area of direct to consumer advertising of pharmaceutical products. It does not.

- The Annex contains a statement about the sort of information pharmaceutical companies are permitted to place on their internet websites about the medicines that they manufacture and sell.
  - Again the text reflects the status quo, in that there are no changes required to the current arrangements in relation to the advertising of medicines in Australia

## **INTELLECTUAL PROPERTY AND GENERIC MEDICINES**

- Under the Intellectual Property Chapter of the Agreement, Australia has reinforced Australia's existing commitment to a strong intellectual property regime that will support and encourage innovation, while still encouraging competition
- The Australian government has protected the interests of generic pharmaceutical manufacturers by:
  - preserving existing arrangements under which generic medicines manufacturers can obtain marketing approval overseas once a patent extension has been granted for the patented product; and
  - retaining the current five years of protection for test data submitted with an application for marketing approval.
- The text does contain an obligation to provide an additional three years of protection to new clinical information, however this refers to the US system and a footnote to the text recognises that Australia's existing data protection system meets our obligations under this text.

- However, the FTA will require some changes for the generics industry.

### **Prevention of marketing through the TGA process**

- It has been agreed that the Therapeutic Goods Administration (TGA) marketing approval process will be changed to ensure that a generic manufacturer cannot enter the market with a generic version of a medicine before a patent covering that product has expired.
- This simply supplements the existing infringement provisions under the *Patents Act* which provide that if a generic company markets a product that is covered by a patent owned by someone else, the patent owner could take patent infringement proceedings under the *Patents Act* to stop the generic marketing the product.

### **Notification**

- It has also been agreed that, in those limited cases where a generic manufacturer considers a patent to be invalid and intends to enter the market before a patent expires, the patent owner will be notified when the generic manufacturer applies to the TGA for marketing approval of the generic version of the patented product.
- The text does not require Australia to implement these obligations in the same way that the US has:
  - In particular, it does not require us to provide for the US system of automatic 30 month injunctions against a generic manufacturer

- The text gives us some flexibility to implement the agreed changes to suit domestic circumstances.
- We believe that we can implement the changes to ensure the likelihood of delaying the entry of generic drugs to the market is very small.

## **PLASMA FRACTIONATION ARRANGEMENTS**

- This issue is dealt with as a side letter to the Agreement.
- Australia has agreed to review Australian blood plasma fractionation arrangements by 1 January 2007.
- While Australian governments (Federal, State and Territory) currently contract with CSL Limited to manufacture most blood products that are used in Australia, it is only sensible that this arrangement is reviewed from time to time.
- The review will be undertaken by Commonwealth, State and Territory governments.
- If there were to be a competitive tender process agreed on as a result of this review, the Australian Government would want to make sure that proposals from any local company such as CSL Ltd were properly weighed against proposals from overseas suppliers to get the best outcome for Australians.
- The Australian fractionation market is likely to attract the interest of more than one overseas supplier. Any procurement process to be considered by the review of our fractionation arrangements would therefore provide an opportunity for a number of bids.

- Decisions in the future, as now, will be based on delivering the safest and most clinically effective treatments for Australians. Australia's policy on self sufficiency in blood products will not be affected.
- Blood plasma products for use in Australia will continue to be derived from plasma collected from Australian blood donors. If at some future date fractionation were to take place offshore there would need to be arrangements to segregate Australian sourced plasma and associated plasma products from those originating in other countries.
- Australia's regulator, the Therapeutic Goods Administration, will continue to regulate the safety of blood products. The TGA will keep regulatory control of standards wherever the fractionation process takes place and whoever is the fractionator.

## **MEDICAL WORKFORCE**

- Commitments in the services chapter of the Agreement establish a framework to promote the mutual recognition of qualifications for a range of professions. There has been concern that this will encourage doctors to go and practice in the US and exacerbate shortages of medical professionals in Australia
- Problems with recognition of qualifications can be a hindrance to the movement of professionals between countries. Australia will benefit overall if these problems are addressed.

- Doctors moving between Australia and the United States will continue to have to meet the medical registration standards that apply in each country. This will not change. However, the Agreement provides a framework for both countries to look for opportunities to streamline the process. This will be done in close consultation with the medical profession.

## **CONCLUSIONS**

- The Free Trade Agreement between Australia and the US will not impair Australia's ability to deliver fundamental policy objectives in health care.
  - the fundamental architecture of the PBS remains unchanged by the Agreement, and the Government's commitment to ensuring affordable access to essential medicines through the PBS is maintained
  - we have preserved an intellectual property system which provides appropriate incentives for innovation while promoting competition
  - the Government is committed for the future, as it always has been in the past, to ensuring an adequate, safe, secure and affordable blood supply. Nothing in the Agreement compromises or lessens that commitment; and
  - the Agreement provides an opportunity for exploring the scope for greater recognition of qualifications of medical professionals in Australia and the United States

- The outcome for the Australian health system is positive. Access by Australians to affordable medicines under the PBS has been maintained and Australians will benefit from faster access to subsidies for new prescription medicines.
- Australia has come through these negotiations without giving ground on any of the fundamentals underpinning the strength of our current system. We can continue to have confidence in the Australian Government's commitment to affordable and accessible health care for all Australians.