THREE PLUS

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15 February 2009

Ms Janelle Saffin, MP
Chair, Joint Trade Sub-Committee
Parliament House
Canberra 2601

Dear Ms Saffin

Formal submission to the Joint Trade-Subcommittee / Manufacturing for Export

We are writing on behalf of Hospira Australia, the GMiA, Mylan, AusBiotech the NWU and the AMWU to request the opportunity to make a **presentation in person** to the Trade Sub-Committee's *Inquiry into Trade and Investment Relations with Asia, the Pacific and Latin America.*

Investigating and removing trade restrictions to Australian generic pharmaceutical exports is aligned with the terms of reference for the Committee's current inquiry. The Australian generic pharmaceutical industry can assist the Inquiry in its investigation into ways to widen and develop our trade relations with the countries of the regions.

Australia currently exports $3.9 billion of pharmaceuticals each year. Generic pharmaceuticals account for at least 12% of Australia's pharmaceutical exports (or 24% of pharma exports where the value-add in Australia is more than just packaging).

The pharmaceuticals industry is Australia's second largest source of manufactured exports and the Inquiry provides an opportunity to outline how Australia can access markets worth at least $49 billion in today's terms over the next ten years by amending the Patents Act 1990.

Provisions in the *Patent Act 1990* governing extensions of pharmaceutical patents deny Australian manufacturers entry to major global markets for between 1-1.5 years after the equivalent patents and their extensions expire in EU and US. This can be up to five years in some markets that do not offer patent extensions, e.g. Canada.

Removing these trade restrictions is in line with a number of recently completed Federal Government reviews such at the Mortimer Report, the National Innovation Systems Review, and the Standing Committee on Industry, Science and Innovation Inquiry into research training and research workforce issues in Australian Universities: *Building Australia's Research Capacity*.

Attached is a submission by the key Australian industry groups and employee organisations supporting the change to Section 78 of the Patents Act 1990.

Please contact me directly so we can prepare the presenters well in advance.

Yours sincerely

Jason Thomas
Principal Consultant – Government Relations
Three Plus Pty Ltd

Submission to the Joint Trade Sub-Committee

Inquiry into Trade and Investment Relations with Asia, the Pacific and Latin America

February 2009

Terms of Reference

The Joint Standing Committee on Foreign Affairs, Defence and Trade shall examine and report on opportunities for expanding Australia's trade and investment relations with the countries of Asia, the Pacific and Latin America, with particular attention to:

- The nature of existing trade and investment relations
- Likely future trends in those relations
- The role that these countries might play in advancing the DOHA round of multilateral trade negotiations in the WTO
- The role of the Government in identifying opportunities and assisting Australian companies, especially those in rural and regional areas, to maximise opportunities in these regions

Submission

- The members of the Generic Medicines Industry Association (GMiA) (including Hospira and Mylan), members of AusBiotech, the National Workers Union (NWU) and the Australian Manufacturing Workers Union (AMWU) request that the Trade Sub-committee recommend an amendment to section 78 of the Patents Act 1990 to enable the Australian pharmaceutical and biotechnology sector to manufacture for export to international markets

- This submission is made under the terms of reference for the Committee's current inquiry that seeks to "…examine and report on opportunities for expanding Australia's trade and investment relations with the countries of Asia, the Pacific and Latin America."

- The proposed amendment does not require Government funding and has the potential to :

    - Open access for Australian businesses to multi-billion dollar global pharmaceutical markets, and
    - Promote Australia as an investment location for establishment of export oriented pharmaceutical businesses.

Manufacture for Export (MfE)

Supporting Australia's Pharmaceutical and Biotechnology Industry

An overview for Australian Governments

First Issued November 2008
(updated 19 February 2009)

Manufacture for Export (MfE) is:

The ability for generic manufacturers to manufacture product for export markets before expiry of the relevant Australian patent term extension

MfE seeks to:

change Australia's patent laws to permit such manufacturing, consistent with its WTO and USA-Australia FTA obligations. MfE is at no direct cost to government and does not impact the commercial rights of Australian patent holders

What we are seeking to achieve

"I said before I became Prime Minister of Australia that I did not want to be Prime Minister of a country that did not manufacture any more. I meant it then, I mean it now and I mean it for the future"

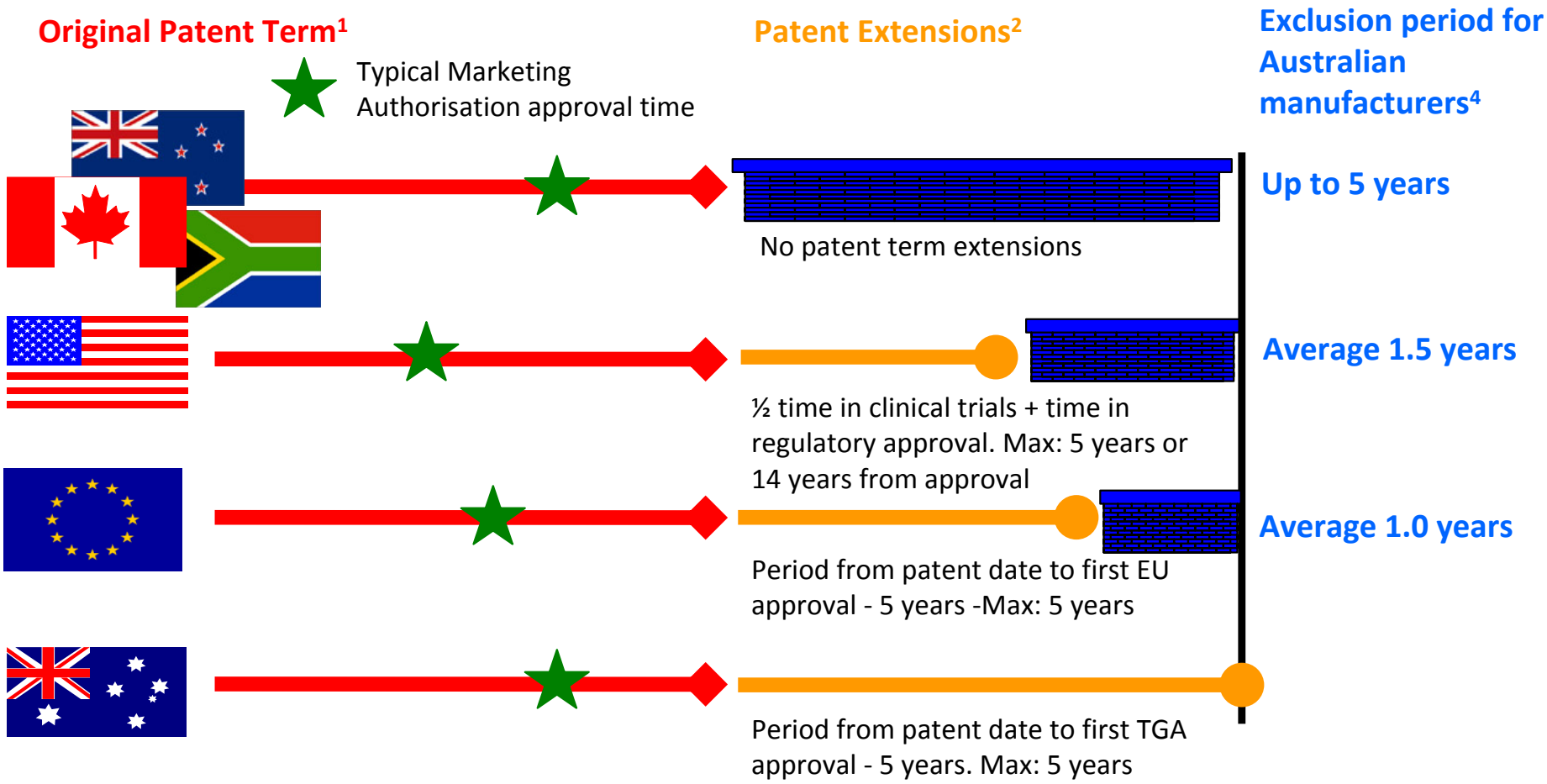
Kevin Rudd, Prime Minister of Australia, 10 Nov 2008[1]

Manufacture for Export (MfE) aims to level the playing field for Australian-based generic pharmaceutical manufacturers versus their international generic manufacturing competitors[2] and in doing so:

- Provide greater security for existing facilities generating $450 million of manufacturing exports each year and employing 1,950 highly skilled workers
- Potentially increase Australia's pharmaceutical exports ($3.9 billion today) by 10%[3]
- Provide valuable manufacturing capabilities, skills and development opportunities for Australia's biotechnology industry
- Internationalising Australia's R&D that is beyond the resources 'boom'

[1] Remarks at the launch of the New Car Plan for a Greener Future Auto CRC Melbourne; http://www.pm.gov.au/media/Speech/2008/speech_0595.cfm;
[2] MfE does NOT aim to reduce the patent protection or commercial value of patents for patentees in Australia or elsewhere
[3] Source: Hospira estimate

Australian generic manufacturers are at a competitive disadvantage compared to overseas competitors



66% pharmaceutical patents expire later in Australia than in comparable countries[3]
22 of 23 extended injectable drug patents expire later in Australia than US or EU[4]

[1] 20 year term being standardised under WTO conventions and TRIPS (Trade Related Aspects of Intellectual Property Rights)
[2] Patent extension exist at the sole discretion of individual nations (no TRIPS requirement) and are generally intended to compensate patent holders for regulatory approval delays. The calculation of, and length of, patent extensions varies by country
[3] Source: Australian Intellectual Property Research Institute, Discussion Paper on Patent Extensions and Springboarding, September 2002
[4] Source: Hospira analysis based on a portfolio of selected injectable pharmaceuticals that are covered by a relevant patent extension

How did Australia end up in this position

1999 - Amendments to the Patent Act (1990) introducing patent extensions created this current manufacturing restriction. 'Springboarding' was also introduced, but only in relation to extended patents

2005 - During the "Action Agenda"[1], industry lobbied for a widening of the Springboarding provisions and MfE (Action 6), however neither action was taken forward into the final recommendation

2005 – During USA-Australia (US-A) FTA discussions, industry lobbied Australian Government. Springboarding was supported, while MfE was not

2005 – US-A FTA included Springboarding as an exemption to infringement

2006 - Patent Act was amended to allow for Springboarding on any patent at any time, not just extended patents

[1] Source: http://www.pharmacouncil.com.au/news_pdfs/PIAA%203rd%20yr%20Imp%20Report.pdf

Springboarding – able to develop but not manufacture in Australia

	Product Development	Product Registration	Commercial Scale Production for Export
Springboarding	✓	✓	×
Manufacture for Export	×	×	✓

Springboarding permits research and development for registration purposes only of generic pharmaceuticals at any time during the term of any Australian patent

It makes financial sense for manufacturing to remain as close as possible to R&D. It also retains valuable skills and knowledge in-country. While springboarding was essential to keep R&D in Australia, those facilities may be lost over time if manufacturing is not also supported

Why have a generic pharmaceutical R&D facility in Australia if you are unable to manufacture in Australia for global markets?

Unintended consequences of Patent Act 1990: a legislated competitive disadvantage

Denies local manufacturers entry to major markets for between 1 to 1.5 yrs[1] after equivalent patents expire

- Market entry delayed by to 5 years in some TRIPS compliant markets (e.g. Canada)

Has forced manufacturing offshore to achieve global launches, impacting jobs, skills and contract manufacturing capacity in Australian pharmaceuticals

An example of this is evidenced by Hospira:

- Hospira established a JV with Zydus Cadilla in India in 2004 to manufacture cytotoxic drugs. Australia is still the only other location Hospira can make these products
- Hospira faces a similar choice about location for selected bio-manufacturing – Australia is currently the only in-house location, however requires MfE to remove competitive disadvantage

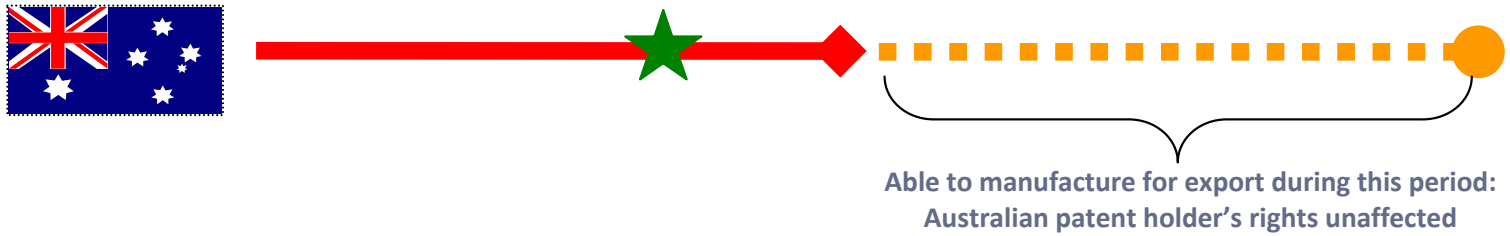
Images of the Hospira / Zydus joint-venture manufacturing facility in, India, Nov 2008

[1] Source: Hospira analysis based on a portfolio of selected injectable pharmaceuticals that are covered by a relevant patent extension

How to amend legislation to allow for MfE

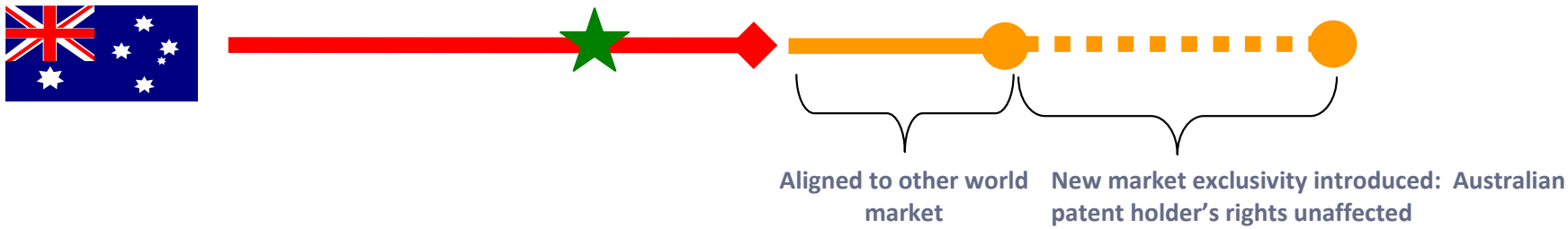
Preferred Approach

Amend s.78 of the Patents Act 1990 to make manufacture for export only an exemption to infringement during the patent term extension



Alternate Approach

Adjust the calculation/expiry of the extension so it is consistent with the rest of the world combined with a period of market exclusivity in Australia to protect local commercialisation rights



The two approaches: dealing with anticipated objections

Anticipated Objection	Preferred Approach	Alternate Approach
Will impact on Australian market monopoly for patent holders	Current patent extension process is not affected and current rights are unaffected	Reduction in patent extension term is supplemented with an equivalent period of market exclusivity
Not permitted under the USA/Australia (US-A) FTA and 'Side Letter'	US-A FTA and side letter only prohibits export of material made under the springboarding exemption	Provide Australia offers patent extensions, the US-A FTA has no requirement on duration
MfE is not consistent with US-A FTA	The US-A FTA expressly allows Australia to introduce a limited exception like manufacturing for export	
Not compliant with TRIPS	TRIPS does not require patent term extensions nor govern how they are to be implemented. It also allows limited exceptions. There is no WTO precedent dealing with limited exceptions during the patent term extension period.	

Australia's pharmaceutical industry is the second largest manufactured product exporter…

Pharmaceuticals are Australia's second largest manufacturing export (after automotive) accounting for A$3.9 billion in 2007[1]

Pharmaceuticals manufacturing accounts for 1% (15,000)[1] of Australia's total manufacturing workforce, but produces almost 10 per cent of Australia's manufactured exports

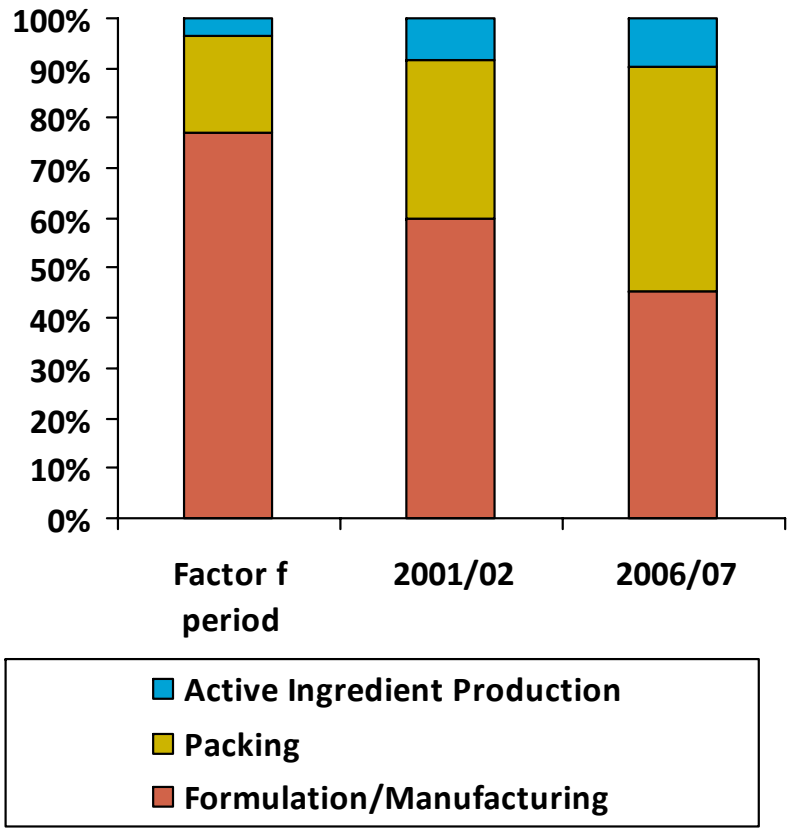
Generic pharmaceuticals represent an important value-add component:

- More than 12% of the total pharmaceutical pharma exports ($450 million)
- Exporting to 60+ markets
- 24% of value-added exports – driven by manufacturing/formulation activities
- 1,950 manufacturing and R&D jobs in Australia[2]

[1] Source: Pharmaceuticals Industry Strategy Group Directions Paper, Sep 2008
[2] Source: Industry sourced information

… and generics are an increasingly important part of the industry

Types of Pharmaceutical Manufacturing
% of value-add (AUD)[1]



Past 10 years has seen significant reduction in the level of 'value-add' pharmaceutical manufacturing

Past 12 months generic industry's export sales were approx. $450 million

- ~12% of Australia's total pharma exports
- ~24% of value-added pharma exports

Other pharma companies are reducing activities in Australia

- **Merck Sharp & Dohme** – to scale back of solid-dose production; refocus on packaging
- **GlaxoSmithKline** – to cease solid-dose manufacture, Boronia, Victoria, production facility
- **Alphapharm** and **Johnson & Johnson** – announced closure of R&D facilities

Generic industry has essentially retained full value-added exports with 95% of exports formulated in Australia

[1] Source: Pharmaceuticals Industry Strategy Group Directions Paper, September 2008

Future growth requires access to global generic markets

While the Australian pharmaceutical industry is ranked 15th in the world, the market accounts for only 1% of the worldwide market value[1]

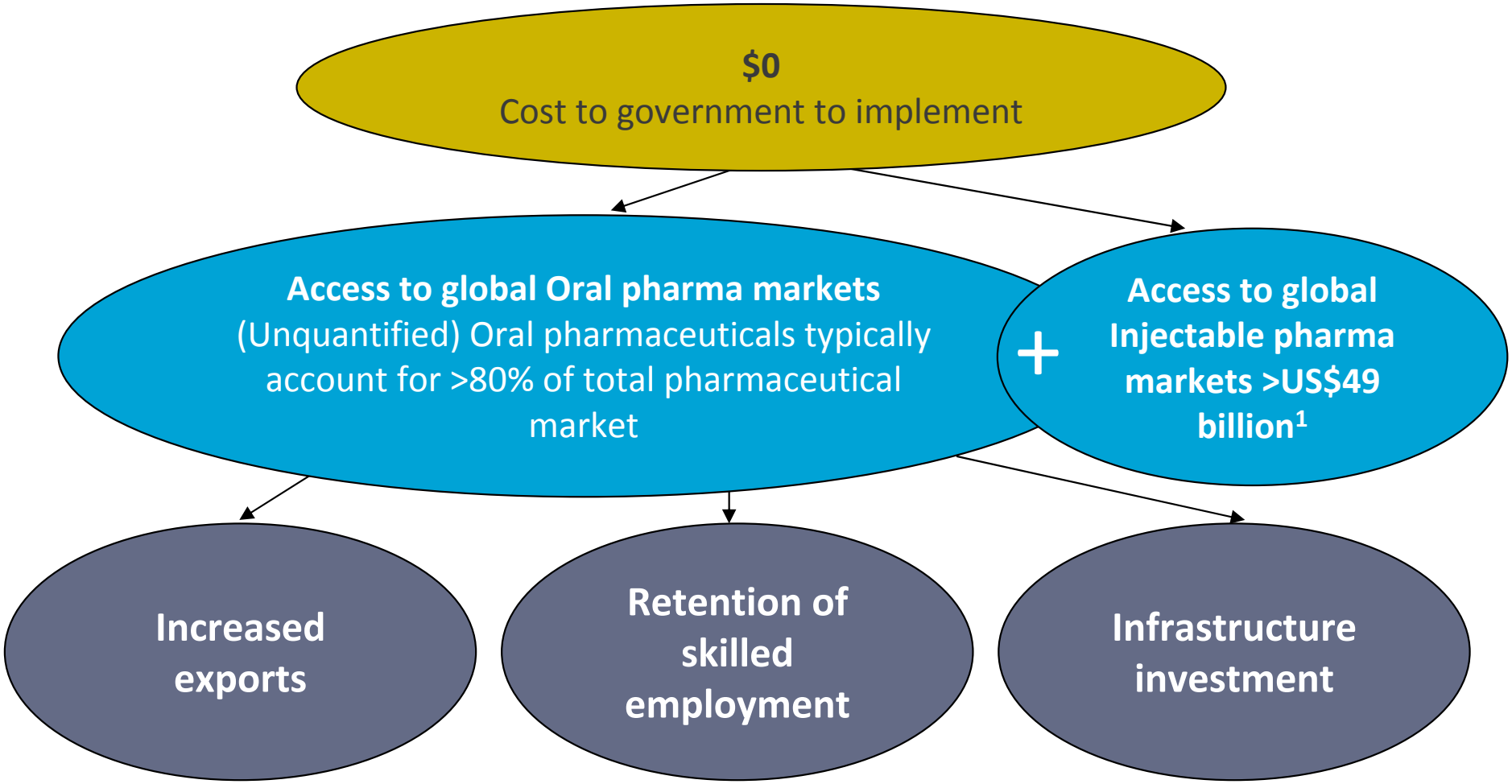
Global generic pharmaceutical market is expected to grow @14%p.a[1].

Gaining access to the worldwide markets immediately after patents have expired is a key success factor for this industry

$110 billion of pharmaceuticals[2] and $45 billion[3] of biopharmaceuticals will come off patent over the next decade

[1] Source: IMS 2009 Pharma Market Outlook
[2] Source: Pharmaceuticals Industry Strategy Group Directions Paper, September 2008
[3] Source: Datamonitor, "Biosimilars Series: Regulatory and development issues – hurdles exist but are surmountable", September 2007

Benefits to the Australian economy



Focused on high 'value-add' production

Attract and retain highly trained science graduates with increased partnerships with universities

Building innovation hubs that kick-start biotechnology companies

[1] Source: Hospira assessment of major markets for high-value injectable pharmaceuticals with patent expiries until 2024

MfE seeks to eliminate a ‘behind the border’ trade restriction

- A provision such as MfE has the effect of trade liberalisation
- As such, MfE is consistent with the spirit of international conventions that seek to promote trade and removal of differences in regulations or barriers that limit trade between nations
- As such, we are supportive of MfE provisions being multilateral – this would be a true “level playing field”

What Australian governments can do to support MfE

We urge you to ask "HOW can this be done?", rather than "Can it be done?"

1. Recognise that MfE creates a level playing field for Australian generic pharmaceutical manufacturers and is the 'missing piece' to Springboarding

2. Support required amendments to the Patents Act 1990 to enable MfE

3. Drive for a decision to implement MfE by April 2009 to allow one known project to be retained in Australia