



2 May 2008

Mr David Mortimer AO  
The Secretariat  
Export Policies and Programs Review  
Department of Foreign Affairs and Trade  
Barton ACT 0221

Dear Mr Mortimer

### **Perspectives on Australia's Export Policies and Programs**

Hospira is a global specialty pharmaceutical and medication delivery company that develops, manufactures and markets products that help improve the safety, cost and productivity of patient care. Hospira's portfolio includes one of the industry's broadest lines of generic acute-care and oncology injectables, which help address the high cost of proprietary pharmaceuticals; and integrated solutions for medication management and infusion therapy. Hospira's broad portfolio of products is used by hospitals and alternate site providers, such as clinics, home healthcare providers and long-term care facilities. In February 2007, Hospira acquired Mayne Pharma to increase its global presence in specialty generic injectable pharmaceuticals.

Hospira is a significant manufacturer of pharmaceuticals in Australia, employing over 1100 staff across three manufacturing and R&D locations and two commercial offices. The majority of Hospira's Australian production is exported, with sales of over 85 active pharmaceutical substances into more than 65 markets including the USA, European Union, China and soon Japan, generating sales of over A\$400 million in 2007 at the point of sale to third parties. Hospira is the leading global supplier of generic oncology pharmaceuticals and Australia remains the primary global manufacturing location for these products, as well as being our regional headquarters for Asia Pacific. A full profile of our Australian based operations forms Attachment 1.

We recommend that your review of Australia's Export Policies and Programs (the Review) consider two key policy areas that impact the continued global competitiveness of Australia's pharmaceutical exports:

1. Intellectual Property regulation and its impact on when Australian manufactured generics become available in international markets; and
2. Free Trade Agreements and their ability to influence market access and assure quality standards

Hospira Pty Ltd  
ABN 11 107 058 320

GPO Box 2507  
Melbourne Victoria 3001 Australia  
Level 3, 390 St Kilda Road  
Melbourne Victoria 3004 Australia  
Telephone 1300 046 774  
International +61 3 8541 5200  
[www.hospira.com](http://www.hospira.com)

## Intellectual Property

Hospira respects the protection of intellectual property rights and in particular, the valuable role of the patent system in providing a fair period of monopoly exploitation to reward and incentivise genuine invention. Despite significant advances in harmonisation of intellectual property laws, Australia's IP scheme poses some significant hurdles for a pharmaceutical company seeking to base its operations in Australia.

For any pharmaceutical company, being able to compete in the international market is essential. Competing successfully means a company has to be able to enter the significant global markets like the US, Europe and Japan and emerging markets like China, India and Korea at the earliest possible market entry date. For a generic pharmaceutical company that date is generally determined by the expiry of the patent for the active pharmaceutical ingredient. Those types of patents are extended in most key markets under special legislative schemes, such as Part III of the Australian Patents Act 1990. These schemes determine the length of the extension to the patent term by reference to the date on which a drug was first approved by the regulatory health authority in that country.

Experience shows that most drugs receive regulatory approval in Australia later than in the major markets around the world and as a consequence, patent extensions tend to expire later in Australia than the equivalent extensions in the other major markets. A generic pharmaceutical company using Australia as a manufacturing and export base is therefore regularly prevented from competing in those overseas markets while manufacturers in those markets, or from other markets such as India that continue to have shorter periods of protection continue are free to launch. Hospira has been forced to establish manufacturing facilities overseas in order to try and overcome this problem. This is a clear situation of lost Australian exports from existing Australian based companies such as Hospira, but it also means that global generic pharmaceutical manufacturers may have in the past and will into the future, bias against the establishment of manufacturing operations in Australia.

There are also some ambiguous limitations on the ability of a pharmaceutical company with research facilities in Australia to export materials during the patent term as part of its research, development and regulatory work (section 119A of the Patents Act). Those ambiguities should be clarified in a manner that allows the greatest reasonable freedom to companies engaged in research and development in Australia, in order to contribute to Australia's standing as a desirable and preferred location for pharmaceutical R&D in both research-based and generic-based products. In that respect, the government should also continue to investigate and support the recommendations of ACIP on the introduction of an experimental use exemption to patent infringement.

Hospira urges the Review to consider whether further reform of Australia's intellectual property system could remove some of these barriers to increased export of generic pharmaceuticals from Australia without damaging or reducing the value of valid intellectual property rights. Specifically, Hospira continues to support legislation that prevents "evergreening" of product protection without genuine, valuable invention. We

disagree with Medicine's Australia's submission to the National Innovation Review that such legislation will allow generic companies to enter markets without penalty before valid patents have expired (see Attachment 2)

### **Free Trade Agreements**

Governments around the world are struggling to contain healthcare budgets in the face of rapidly aging populations and increasingly expensive originator pharmaceuticals and biopharmaceuticals. To increase headspace to afford new medicines or in some cases to enable greater access to medicines at all, they need vibrant and competitive generic and biogeneric markets in order to contain pharmaceutical costs once valid patents have expired. Almost universally, they are adopting strategies and policies to increase generic usage and IMS projects that the global generic market will grow 2-3 times faster than the overall pharmaceutical market in the next 5 years.

On the other hand, recent concerns about contaminated heparin and low molecular weight heparin products highlight the importance of appropriate quality standards to assure patient safety. Regulatory agencies' ability to monitor Good Manufacturing Practice (GMP) around the world is becoming increasingly stretched as global supply chains seek lower cost manufacturing locations. Unfortunately, there is limited co-operation between agencies and it is well known that while many manufacturing sites receive multiple visits in quick succession from regulatory authorities when a product is first approved, many others may not have been inspected for many years. In addition, regulatory and quality standards still vary considerably from market to market and in many cases may not have kept pace with the latest developments in science.

Australia has a relatively mature generic market and has achieved mid-range generic usage. It has been quite successful in containing pharmaceutical costs. The Therapeutic Goods Administration (TGA) is a well respected regulatory and quality manager that is mutually recognised by other top tier quality markets such as the UK and Canada, though it is not immune to the shortage of GMP auditors.

Australia, and Australian generic pharmaceutical exporters such as Hospira, Mylan (Alphapharm) and Sigma are thus uniquely placed to participate in the growing market for quality, affordable generics, provided artificial or non-science based barriers to generic adoption can be removed in our target markets. By considering the needs of generic pharmaceuticals in negotiations on regulation and standards, intellectual property, general business environment and tariffs as part of Australia's Free Trade Agreement (FTA) program, Hospira believes Australia has a unique opportunity to:

- Enhance generic pharmaceutical exports from Australia. This would help secure investment and employment in R&D and manufacturing in knowledge industries for Australia
- Enhance quality generic usage in partner markets, benefiting the partner through more affordable, quality healthcare
- Establish greater co-operation between regulatory authorities to achieve greater reach and standardisation of pharmaceutical quality assessments and reduce the overall cost of monitoring pharmaceutical supply chains

We urge that the Review support the continuance of bilateral FTA's as well as multilateral FTA's as a mechanism for opening up more markets to Australian pharmaceutical exports. In particular, these FTA's should strive for:

1. Regulatory collaboration and mutual recognition of various regulatory activities, including GMP inspections; product release testing; chemistry, manufacturing and control assessments; active pharmaceutical ingredient reviews; and even mutual recognition of drug approvals. There are significant resource efficiencies and/or cost recoveries to be gained from such collaboration with developed regulatory markets and opportunities to increase quality standards in less regulated markets, thereby reducing the cost differential Australian manufacturers often find entering those markets
2. Regulatory harmonisation to eliminate requirements that cannot be supported scientifically or which represent non-tariff barriers to trade
3. Avoiding introducing any further restrictions on the Australian Parliament's ability to legislate on intellectual property issues, and in particular, do not use any FTA as a means to implement 'TRIPs-plus' measures; and
4. Removal of other non-tariff barriers to trade or impediments of efficient internal pharmaceutical markets

The specific issues and opportunities vary greatly from market to market. The breadth of issues that could be tackled in FTA's is illustrated by the example of Japan which forms Attachment 2. Markets that Hospira is targeting for increased export volumes of Australian made oncology generics and biogenerics that are the subject of existing, actively negotiated or potential future FTA's include Japan, Korea, China, USA and ASEAN. Hospira intends to make direct submissions to the Asian FTA negotiating teams in particular outlining specific opportunities in each of these markets.

Hospira believes that continued focus on intellectual reform, regulatory harmonisation and reduction of non-tariff barriers to trade both unilaterally and through our Free Trade Agreements can help Australia enhance investment and employment in pharmaceutical R&D and manufacturing, drive exports of generic pharmaceuticals (especially into Asia), and help establish Australia as a centre of excellence in providing quality, affordable access to pharmaceuticals. We would be pleased to discuss the issues raised in this submission with the Export Policies and Programs Review should further clarification be required.

Yours sincerely,



Tim Oldham  
President, Asia Pacific

**Attachment 1**  
**Hospira Australia (incorporating the former Mayne Pharma Ltd)**

Hospira, Inc. is a global specialty pharmaceutical and medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that help improve the productivity, safety and efficacy of patient care. With over 70 years of service to the hospital industry, Hospira's portfolio includes one of the industry's broadest lines of generic acute-care injectables, which help address the high cost of proprietary pharmaceuticals; integrated solutions for medication management and infusion therapy; and the leading U.S. injectable contract manufacturing business. Headquartered north of Chicago in Lake Forest, Ill., Hospira has approximately 15,000 employees and 17 manufacturing facilities worldwide. In late 2006, Hospira acquired BresaGen Ltd as part of its global biogenerics program. In February 2007, Hospira acquired Mayne Pharma Ltd to become the global leader in speciality injectable generic pharmaceuticals. Hospira's news releases and other information can be found at [www.hospira.com](http://www.hospira.com).

Hospira operates three principle manufacturing and R&D sites and two commercial offices in Australia. In all Hospira employ more than 1100 staff, including approximately 750 in manufacturing and 200 in R&D. They have just under 220 employees in Adelaide, a small commercial office in Sydney and the remaining staff are based in Melbourne or are selling products to hospitals throughout the country. Hospira invests over A\$30million per year on R&D in Australia and is a P3 participant contracted to earn A\$10million between 2004 and 2009.

Hospira are the leading supplier of injectable generic pharmaceuticals to Australian hospitals, selling over 85 active drug substances. Hospira also supply some of the world's leading infusion delivery and medication error reduction technology to make Australian hospitals safer and more efficient for patients and healthcare professionals. Total sales in Australia exceeded A\$150 million in 2007.

Hospira operate three manufacturing and R&D sites employing world class technology, staff and processes to deliver medicines to the leading international and local quality standards. The two manufacturing facilities are approved by TGA, FDA and European regulatory authorities. These manufacturing plants supply products to more than 65 countries around the world including Australia, US, Canada, and the major European markets. Hospira plan to introduce Australian manufactured products to the Japanese market very soon.

Through predecessor companies, Hospira have been manufacturing injectable pharmaceuticals in Melbourne since 1915, and chemotherapy agents since 1985. The current facility at Mulgrave specialises in development and manufacture of injectable oncology and cancer support drugs and is Hospira's key global site for these activities. Over A\$50 million has been invested in oncology manufacturing capability at this site in recent years and more than A\$400million of oncology and oncology support products are produced in this facility each year. It also manufactures a range of other generic injectable pharmaceuticals.

Hospira's presence in Adelaide goes back to the establishment of FH Faulding & Co in 1845. A facility at Salisbury specialises in modified release oral pharmaceuticals and provides contract product development services for Australian biotech as well as overseas pharmaceutical companies. This business is focused on export of services and products. A second Adelaide facility, formerly Bresagen, specialises in the development of biological drugs and is a key part of our global biogenerics strategy.

## Attachment 2

### Evergreening of pharmaceutical product patents

Hospira supports legislation that prevents the prosecution or grant of patents that do not offer genuine valuable invention and thus represents an abuse of the patent system (so called “evergreening”).

Medicines Australia’s submission to the National Innovation Review has argued that current legislation designed to prevent “evergreening” would enable generic companies to enter a market before a patent has expired (see report below)

Hospira respects the protection of intellectual property rights for genuine valuable invention and will not knowingly enter a market before the expiry of a patent it believes is valid and infringed. However, Hospira also believes that patents that do not offer genuine useful invention and are prosecuted solely to artificially extend patent monopolies are an abuse of the patent system and fully supports the Australian Government in any initiative to prevent such abuses occurring.

Hospira does not believe that such reform will negatively impact investment in pharmaceutical and healthcare R&D in Australia and supports other initiatives that will stimulate this important knowledge industry, of which we are a part. Further, allowing such patents to remain as barriers to entry in Australia could also prolong the period in which generic manufacturers are unable to exploit expired patents in export markets

The Australian Financial Review  
www.afr.com • Friday 2 May 2008

# Call for innovation injection

John Breusch

The pharmaceuticals industry has called for the creation of a fund to support scientific research and for a cut in the company tax rate, among a raft of proposals to boost innovation in the economy.

In a submission to the federal government’s review of the national innovation system, Medicines Australia warns the country’s capacity to attract investment for health research and development is declining rapidly.

It points to the recent decision by medicines giant Merck Sharp & Dohme to scale down its local operation, at a loss of 60 jobs, as evidence of a broader malaise in Australia’s attractiveness as an investment hub.

“Multinational corporations are relocating manufacturing and research and development to emerging economies, which already offer considerable (and still growing) advantages in both regards,” Medicines Australia said.

“In the very recent past, Australia’s apparent competitive advantages lay in its ability to attract precisely these sorts of companies. The Merck Sharp & Dohme example demonstrates that either Australia has already lost these advantages, or, at the very least, faces the real danger of losing them very soon.”

Medicines Australia argues that although Australia’s 30 per cent company tax rate is close to the Organisation for Economic Co-operation and Development average, OECD countries are not Australia’s true competitors in pharmaceuticals R&D.



Medicines Australia warns we are losing our competitive edge. PHOTO: JESSICA SHAPIRO

“In the innovative medicines industry, our direct competitors are Ireland, Singapore, South Korea, the Philippines, and increasingly the United Arab Emirates, India, and China,” it said. “The average effective corporation tax in these countries is 15 per cent.”

**Multinationals are relocating to emerging economies.**

Medicines Australia proposes the company tax rate should be phased down from 30 per cent to 20 per cent over three years.

To address concerns that universities lack the funding to provide adequate technical training, the group has also proposed the creation of a fund that would draw on companies, philanthropic organisations and government to provide endowments for professorships in fields like health economics, research methodologies, and clinical sciences.

It also urges the government to scrap a law introduced at the behest of former Labor leader Mark Latham that aims to stop “evergreening” — where drug companies repeatedly introduce minor changes to their products to extend the life of patents.

Medicines Australia argues the Latham amendment allows generic drug makers to enter a market before a patent has expired.

It is a submission to the review, health R&D peak body Research Australia calls for a doubling of funding to the National Health and Medical Research Council from 2010.

### Attachment 3

## Opportunities to enhance Australian pharmaceutical exports through the Australia-Japan FTA

Japan is the second largest pharmaceutical market in the world (~US\$60 billion), yet has one of the least developed generic markets. Generics represent around 17% of the market by volume (compared with 50-70% in Germany, UK and US), but even with this low penetration the market that is still worth US\$3 billion today. The Japanese government has made a commitment to increase generic usage to 30% by volume by 2012. Barriers to increased generic usage range from regulatory and IP limitations to market access, to patient and healthcare provider attitudes and incentives to generic usage. The government has begun to address some of these but not all of these, and aspires to create several globally competitive generic companies based in Japan. Several US, European and Indian-based generic companies have begun operations in Japan. Hospira began selling US sourced generic pharmaceuticals in Japan in 2007 and has submitted applications for Australian sourced generic pharmaceuticals that should be approved for sale from 2009 onwards.

We see the four areas of opportunity in the Japan-Australia FTA that would benefit Hospira, Australia and Japan:

1. **Regulatory collaboration.** Australia's TGA and Japan's Pharmaceutical and Medical Devices Administration (PMDA) have a long standing exchange on Good Manufacturing Practice (GMP). Extending this to full mutual recognition of GMP would have the following benefits
  - Eliminate dual inspections of foreign facilities. Currently the TGA and PMDA will both be conducting audits and inspections of the same manufacturing facilities in India, China and other locations
  - Eliminate the cost of duplicate release testing, at least for product manufactured in Australia or Japan. Currently both countries require repeat testing of products manufactured in markets without a mutual recognition agreement. Australia has such an agreement with the EU, but not Japan. Japan has no such agreements
2. **Regulatory harmonisation.** The PMDA has several requirements of generic manufacturers that would not be required of Japanese generic manufacturers entering Australia. In some cases, these requirements are more properly the responsibility of pharmaceutical purchasers, not regulators and therefore constitute non-tariff barriers to trade that should be eliminated in a free trade agreement
  - Excessive or time consuming regulatory requirements not demanded by the TGA include
    - A requirement to submit full shelf-life stability data for products claiming less than three years shelf life (TGA only requires six months stability data)
    - Only two generic pharmaceutical approval dates each year (January and July) compared with no limits for originator pharmaceuticals (TGA has no limits for any product type)

- Spontaneous reporting of literature reports of adverse events from anywhere in the world outside Japan even if the event cannot be attributed to the applicant's drug
    - Regulatory requirements that "mandate" what are more properly commercial and clinical choices that are the scope of pharmaceutical purchasers include
      - A requirement to maintain supply for 5 years from launch, regardless of market viability, with penalties including cancellation of registrations
      - A requirement to provide all the approved strengths and formats of the originator, regardless of the actual market usage of those strengths and formats
      - Restrictions on the ability to supply novel formulations and strengths without extensive clinical justification and despite any IP that may exist around originator formulations
3. ***Intellectual Property reform.*** There are several areas where Japanese IP law creates unfair monopoly protection that would not be possible in Australia.
- Multiple patent extensions on multiple patents (including method of treatment/indication patents) are possible in Japan, versus a single extension on a single patent covering the product in Australia. This obviously has the potential to create perpetual protection without litigation.
  - Japan also offers a form of patent linkage to registrations that is far more onerous than the Australian patent certification process. Specifically, applicants must satisfy the PMDA that any relevant "substance" patents will expire before product approval and that supply will not be put at risk by other patents related to formulations, etc that may run longer than product approval.
  - In addition, re-examination periods (the Japanese equivalent of data exclusivity) attach to specific indications and are longer than in Australia (6-8 years versus 5 years)
  - On the positive side, Japan appears to have a much more efficient and cost effective patent litigation system than Australia resulting in potentially faster clarification of the patent landscape
4. ***Other non-tariff barriers to trade and impediments to efficient internal markets*** that should be eliminated include
- Price negotiation for pharmaceuticals. Manufacturers are not permitted to negotiate price directly with hospitals in Japan. Wholesalers, who carry multiple products from multiple companies, are the only parties permitted to negotiate price with hospitals. This reduces transparency and eliminates one of the most significant elements of the generic value proposition: value for money

FTA outcomes that would begin to address these issues could include commitments to Mutual Recognition Working Groups between PMDA and TGA; intergovernmental working groups on methods to promote and manage increased generic usage; and commitments to reduce specific non-tariff barriers to competitive pharmaceutical markets