Stuart James
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China FTA Study Taskforce
Department of Foreign Affairs and Trade

Dear Sir/Madam

Re: China FTA submission – impact on generic pharmaceutical industry

I refer to the request for submissions made by the Department of Foreign Affairs and Trade (DFAT) regarding the feasibility study for a Free Trade Agreement (FTA) with China. I also refer to a meeting between the Department of Industry, Trade and Resources and members of Mayne's generic pharmaceutical business, Mayne Pharma, that took place in July 2004. Given the significant potential consequences on Australian-based pharmaceutical companies arising from an FTA with China, please consider the following comments carefully. Mayne Pharma would be happy to discuss them in more detail should you wish.

Background and introduction

Mayne Pharma is an international specialty pharmaceutical company which develops, manufactures and sells generic injectable pharmaceuticals to more that 50 countries around the world. We concentrate primarily on anti-cancer medicines and our business employs more than 1,800 people around the world with approximately 1,100 of those based here in Australia. Our primary manufacturing facility is located in Mulgrave, Victoria and we were named the Victorian Exporter of the Year as well as the Australian Large Advanced Manufacturer of the Year in 2004. We are the seventh largest pharmaceutical company in Australia, based on sales, and in our chosen niche of generic, injectable oncology medicines, we are the market leader in Australia, Western Europe and Canada.

We develop and manufacture pharmaceuticals to meet strict regulatory requirements in developed countries such as those set by the United States Food and Drug Administration (USFDA), the European Medicines Agency (EMEA) and the Therapeutic Goods Administration (TGA) in Australia.

Mayne Pharma's and indeed generic pharmaceutical manufacturer's success is dependent on the following factors:

- Developing and manufacturing new generic products as early as possible so that Mayne Pharma may enter the market as soon as intellectual property restrictions for the innovator product expires;
- Complying with quality and regulatory requirements such as those imposed by the USFDA, EMEA and TGA for both our manufacturing facilities and the marketed pharmaceutical products in those locations; and
- Managing our business as efficiently as possible so that Mayne Pharma remains profitable as the prices for our products naturally erode during their life cycles.

Due to differences in patent laws, quality and compliance requirements and cost structures between China and Australia, we are concerned that if these were not adequately addressed in trade negotiations, Australian manufacturers of generic medicines would be placed at a significant competitive disadvantage to our Chinese peers.

Exports to China

Mayne Pharma currently exports a number of its finished products to China. While the Chinese pharmaceutical market is certainly very large, the quality and compliance standards for products sold in China are not to the same standard as those required by the TGA, EMEA or the USFDA. As a result, domestic manufacturers in China are able to produce medicines at prices below ours because they do not need to maintain the same high standard of quality and compliance systems, and those systems are continually being improved for medicines sold in western markets. This lower cost structure puts Chinese companies at an unfair cost advantage. As a result, the Chinese market opportunity for Australian generic pharmaceuticals manufacturers is far more limited than it would first appear.

Imports from China

In regards to importing Chinese approved generic pharmaceuticals, Australian generic pharmaceutical manufacturers would be at a similar cost disadvantage because of the lower manufacturing and quality and compliance systems required for pharmaceuticals manufactured in that country. If imports were "opened" under an FTA with China, this situation would require significant surveillance by the TGA to ensure the quality of the products were at a standard acceptable in this market.

Australian patent law restrictions – development and manufacturing for export

Finally, due to differences between Chinese and Australian patent laws, Chinese companies would be able to develop and manufacture generic pharmaceuticals for export prior to Australian companies being able to develop the same medicines.

As China did not previously allow the patenting of the drug itself, Chinese manufacturers are already able to manufacture a number of drugs without fear of infringement. Australian companies are precluded from making those same drugs due to the existence of a relevant patent in Australia. Even where there is a patent in China, it has been widely acknowledged that patents are rarely enforced in China. Further, China does not allow extensions of the patent term, so the same pharmaceutical patent will generally expire later in Australia than in China. In summary, the Chinese patent system is not as stringent as many western countries, including Australia, and puts Chinese manufacturers of generic drugs at a significant advantage in terms of when products may be developed and when products may be manufactured for export.

In Australia, patent laws restricting the development of generic medicines for export during the life of the Australian patent (including any patent extension) are far more onerous than most countries around the world including China, Canada, and New Zealand. Further, due to the Australian patent laws regarding how extensions to patent terms are calculated, a pharmaceutical patent in Australia typically expires long after the equivalent patents have expired in most other markets around the world.

For example, New Zealand and Canada have no patent extensions at all. In addition, development of a generic product in those countries can occur at any time during the life of any patent relating to the pharmaceutical product (the so-called "springboarding" provisions).

As a further example, the United States has (i) generally shorter patent extensions and (ii) more liberal springboarding provisions than exist in Australia.

In these other jurisdictions, generic pharmaceutical companies are better placed both to begin developing generic pharmaceuticals prior to the expiry of the patent protection, and to begin manufacture of those products sooner due to earlier expiring patent protection. This means that generic companies in those jurisdictions are able to manufacture the product for export to countries where the patent protection period has expired (or in some cases where patent protection never existed), at an earlier date than an equivalent Australian generic pharmaceutical manufacturer.

Since accessing markets for generic pharmaceuticals as early as possible and as quickly as possible is a key success factor for our business, the Australian patent laws already put Mayne Pharma at a significant commercial disadvantage to many of our competitors around the world.

We have previously highlighted this issue to DITR and The Hon. Ian Macfarlane, and would appreciate the opportunity of presenting a proposal to you about how Australia could level the playing field in this area to support a vibrant generic pharmaceutical industry.

In summary, we believe the current trade arrangements with China work well as evidenced by the commercial relationships we have developed with several suppliers and customers in China that date back more than 10 years. We do not see additional benefit arising for the generic pharmaceutical industry should an FTA with China be agreed.

Should you have any questions arising from this letter, please do not hesitate to contact our General Manager Corporate Relations, Mr Larry Hamson on (03) 9868 0380.

Yours sincerely

Stuart James
Group Managing Director and Chief Executive Officer