

Japan FTA Task Force  
Department of Foreign Affairs and Trade  
RG Casey Building  
John McEwen Crescent  
Barton ACT 0221

7 November, 2007

To Whom It May Concern:

Thank you for the opportunity to contribute to your consideration of issues relating to the negotiation of a Free Trade Agreement with Japan (FTA). AstraZeneca Australia views the FTA as an opportunity for Australia to strengthen our position in relation to exports of manufactured pharmaceutical goods to Japan.

AstraZeneca Australia manufactures and exports high value manufactured goods to 37 countries. Japan is a major destination, with the value of exported goods steadily rising in recent years. Around 500 people are currently employed in our manufacturing facility, serving in the full range of functions across the manufacturing supply chain.

We believe the FTA has the potential to further develop our export relationship with Japan. While no formal bilateral arrangements currently exist in relation to the trade of manufactured pharmaceutical goods, the FTA provides an opportunity to formalise current arrangements that ensure the continued export of Australian manufactured goods to Japan.

#### Recognition of Australian Good Manufacturing Practice

Japan is not a member of the Pharmaceutical Inspection Cooperation Scheme (PICS) and Australia does not maintain a Mutual Recognition Agreement (MRA) with Japan in relation to certification of Good Manufacturing Practice. Consequently, while Japan does rely on the Therapeutic Goods Administration's (TGA) certification of Good Manufacturing Practice (GMP) for Australian manufacturers, Australia does not recognise Japan's GMP certification of Japanese manufacturers.

Japan's continued recognition of Australian GMP certification will remain a key factor in ensuring our ongoing ability to export manufactured pharmaceutical goods to Japan in a timely and internationally competitive manner. AstraZeneca understands that the Commonwealth does not intend pursuing an MRA with Japan, particularly given Japan is not a member of the PICS. However, our manufacturing for Japan is already characterised by unique and arduous quality assurance processes. Any decision by Japan to no longer recognise Australian certification of GMP would lead



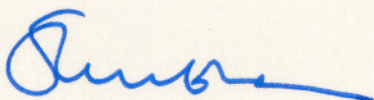
to duplication of testing already conducted in Australia and add significant cost to our manufacturing process and cause delays that would jeopardise our competitiveness to supply product to Japan. This would substantially undermine the future prospects of our North Ryde manufacturing facility, especially in an increasingly cost-constrained global environment.

Australia-Japan MoU

While Australia and Japan signed a Memorandum of Understanding (MoU) in 1993, which has expired, it was only an agreement to exchange information and did not extend to mutual recognition of GMP. Yet the expired MoU formed a basis for Japan's acceptance of Australian certification of GMP. Accordingly, AstraZeneca would support the renegotiation of the MoU under the auspices of the FTA. The MoU would serve as an important device for ensuring continued ongoing exports from Australia, through the exchange of important and relevant information, and a possible framework for a future MRA in the circumstances where Japan was to become a member of the PCIS.

Once again, thank you for the opportunity to contribute to your consideration of issues relating to the FTA. Please do not hesitate to contact Mr Paul Cross, Corporate and Public Affairs Manager, on (02) 9856 8808 with any questions regarding the issue identified in this submission.

Kind regards,



Stuart Anderson  
Director, Supply and Manufacturing

cc. Michael Schwager, General Manager, Pharmaceuticals and Biotechnology  
Branch, Department of Industry, Tourism and Resources