

Senate Standing Committee on Economics
ANSWERS TO QUESTIONS ON NOTICE
Innovation, Industry, Science and Research Portfolio
Budget Estimates Hearing 2009-10
01 June 2009

AGENCY/DEPARTMENT: INNOVATION, INDUSTRY, SCIENCE AND RESEARCH

TOPIC: Generics/Patents

REFERENCE: Written Question– Senator Abetz

QUESTION No.: BI-3

There have been calls by Generic Medicines Industry Association (GMIA), the National Union of Workers and Hospira to change the laws as it relates to generics for export.

- 1) Is the Government considering making this change?
- 2) If not, can you explain the situation as it stands and why a change would be undesirable?
- 3) Please explain the so-called “Latham amendment” and their effect on AUSFTA?
- 4) Is it a fact that these Labor amendments allow market entry by generics before patent expiry without prior notice to the patent holder?
- 5) How do this compare to the US, UK etc?

ANSWER

- 1) The company Hospira, the Generic Medicines Industry Association (GMiA) and others have raised concerns with Government that current patent laws prevent the manufacture of generic drugs by Australian companies for export, also referred to as “manufacture for export” (MFE). Hospira and other generic companies seek amendment of Australia’s patent laws to allow manufacturing for overseas markets in which patents have expired, or never existed. The Government is considering its position and has not made a decision on MFE.
- 2) The Government has not made a decision on MFE. However, any decision could have implications for foreign investment in Australia more generally. There are policy implications to consider including Australia’s broader industry development, investment, trade and health objectives as well as patent law. What is being proposed is not a simple or minor change. MFE raises complex issues, both internationally and domestically, and a thorough analysis of these issues is being undertaken.
- 3) The Latham Amendments introduced sections 26C and 26D into the *Therapeutic Goods Act 1989*. As this question relates to legislation that is the responsibility of the Minister for Health and Ageing, this question should be asked of the Health and Ageing Portfolio.
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