Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-2012, 15 February 2012

Question: E12-239

OUTCOME 2: Access to Pharmaceutical Services

Topic: PATENTS

Written Question on Notice

Senator Heffernan asked:

What is the Department of Health and Ageing doing with regard to patent misuse, where the period of patent protection is renewed for so-called innovations that amount to little more than tinkering or involve minor modifications to the delivery of the drug?

Answer:

The Department of Health and Ageing (the Department) has no responsibility for intervening in cases of actual or perceived patent misuse, which are commercial matters. Filing a new patent application for a new formulation or use of an existing pharmaceutical is allowable under patent law in Australia and internationally. If the new formulation or use is sufficiently novel and inventive to meet the criteria under the *Patents Act 1990*, then it can be protected by law. However, it is open to a court to find that a patent does not meet the requirement of the Act, including that it is not novel and inventive, and to order that the patent be revoked.

Once the court's decision is advised, the Department ensures that this outcome is reflected in the Government's pricing policy for the medicine in question, which may include the possibility of price reductions following the market entry of generic products in response to a court decision that an innovator pharmaceutical company's patent is invalid.

The Government has also committed to strengthening Australia's patent system through the *Intellectual Property Laws Amendment (Raising the Bar) Act 2011* that was recently passed by the House of Representatives. The Act includes reforms to raise inventive step and disclosure requirements in patent applications and to expand the grounds available to the Commissioner of patents for review of patents both before and after grant.

Within this legal framework the Department is working with the generics industry to identify and resolve any potential adverse impacts on timely listing of generic medicines on the Pharmaceutical Benefits Scheme (PBS) arising from innovator patent extensions. The intent of this work is to improve certainty in the pathway to market for the generic companies, and to therefore minimise the potential for delays to PBS savings. While the Department is committed to assisting with this process it will take time to ensure that any resulting changes to PBS listing processes, if required, do not put at risk the safety of patients.