

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009*

#### Proclamation

Subsection 2(1) of the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009* (the Act) provides that Schedule 3 to the Act commences on a single day to be fixed by Proclamation. Item 3 of subsection 2(1) provides that if any of the provisions of Schedule 3 do not commence within the period of six months beginning on the day the Act receives the Royal Assent, they commence on the first day after the end of that period. The Act received the Royal Assent on 17 June 2009.

The purpose of the Proclamation is to fix 1 December 2009 as the day on which Schedule 3 to the Act commences.

Schedule 3 to the Act replaces the existing “fit and proper person” test in the *Therapeutic Goods Act 1989* (the TG Act) with more specific statutory grounds for the making of decisions in relation to the manufacturing of medical devices and other therapeutic goods. Schedule 3 will also allow the Secretary of the Department of Health and Ageing (the Secretary) to require information from applicants for and holders of manufacturing licences and conformity assessment certificates regarding their suitability to retain such licences or certificates.

The existing fit and proper person test requires the Secretary to consider a broad range of conduct (including third parties’ conduct) by a broad range of persons, exercise significant discretion and balance relevant factors. It has been difficult to administer and criticised by some in the industry as complex and intrusive. The new requirements are narrower, more transparent and are expected to be easier to administer.

Public consultation on proposed changes to the existing “fit and proper person test” occurred during the development of the proposed joint regulatory scheme for therapeutic goods between Australia and New Zealand, which was postponed in July 2007 as a result of the New Zealand Government’s decision not to proceed with their enabling legislation due to insufficient parliamentary support. Further consultation occurred in mid 2008 following the Australian Government’s decision to pursue reforms to the Australian therapeutic goods regulatory framework while the trans-Tasman scheme remained on hold.

The Proclamation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.