



## Therapeutic Goods Amendment Bill (No. 3) 2006

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## **Therapeutic Goods Amendment Bill (No. 3) 2006**

**Date introduced:** 11 May 2006

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** On the day of Royal Assent

### **Purpose**

The Bill proposes amendments to the *Therapeutic Goods Act 1989* (the Act) to allow for applications for licences to manufacture medicines, blood and tissues, to be lodged electronically with the Therapeutic Goods Administration (TGA).

### **Background**

#### **Licence requirements**

In Australia the *Therapeutic Goods Act 1989* requires, with certain exceptions, that manufacturers of therapeutic goods hold a licence.<sup>1</sup> A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the *Therapeutic Goods Act 1989*).<sup>2</sup>

In order to obtain a licence a manufacturer must demonstrate compliance with manufacturing principles including relevant Codes of Good Manufacturing Practice (GMP) and Quality Systems. Compliance is ascertained by regular onsite audits undertaken by the TGA.<sup>3</sup>

Under subsection 37(1) of the *Therapeutic Goods Act 1989*, an application for a manufacturing licence must be made in writing in accordance with a form approved by the Secretary.

The proposed amendments will remove the requirement for an application for a manufacturing licence to be made in writing, and instead permit the electronic lodgement of an application. The amendments will make section 37 consistent with other provisions in the Act that permit the electronic lodgement of applications or information, using software that is compatible with the systems used by the Department of Health and Ageing.<sup>4</sup>

#### **Basis of policy commitment**

On October 11 2004 the TGA implemented a new computerised system called the Manufacturer Information System (MIS) to provide for more efficient processing of the

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different types of applications made to the various areas of the TGA.<sup>5</sup> This was part of a broader process to convert TGA information systems to an e-business format, and was in line with the Government's e-government strategy.<sup>6</sup> The new MIS is designed to eliminate paper forms and allow for electronic application of:

- manufacturing licences for medicinal products,
- certification by audit of overseas medicines manufacturers,
- variations to each of the above, and
- clearance certification of overseas medicines manufacturers by assessment of GMP evidence provided by an overseas regulatory body.<sup>7</sup>

The benefits associated with the electronic lodgement of manufacturing licence applications were highlighted in the second reading speech of the Bill; in particular, that the amendments will allow manufacturer's to monitor progress with their licence applications and electronically submit requests for amendments to their licences.<sup>8</sup> Further, the second reading speech makes clear that an electronic licence application will not require any additional information beyond that already required by the current paper application process.<sup>9</sup>

#### Audit report

The introduction of the MIS in October 2004 preceded the release of an Australian National Audit Office (ANAO) audit report into the Regulation of Non-Prescription Medicinal Products by the TGA, in December 2004.<sup>10</sup> The audit assessed the TGA's regulation of non-prescription medicine products, and in particular, the systems, procedures and resources used to manage, monitor and confirm compliance with requirements for manufacture of non-prescription medicine products. The audit report was critical of the information management systems and processes employed by the TGA, including its data management, documentation and recordkeeping procedures, and recommended that these systems be improved.<sup>11</sup>

As noted above, the TGA had been progressively implementing a major information systems project in support of its regulatory activities. Consequently, the Department of Health and Ageing in its response to the audit, argued that many of the issues raised by the ANAO in the audit were being addressed.<sup>12</sup> Nevertheless, the Department agreed to all the recommendations made in the audit report and engaged the consultants Deloitte's to review implementation progress.<sup>13</sup> The subsequent Deloitte's report, issued in June 2005, found that although the TGA had planned activities to address all the audit recommendations, none had been fully implemented at that time.<sup>14</sup>

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## Financial implications

### Standing appropriations

There is no financial impact, according to the *Explanatory Memorandum*.

## Main provisions

### Schedule 1 – Amendments

**Item 1** amends paragraph 37(1)(a) of the Act, which currently requires a manufacturer of medicines, blood or tissues to lodge an application in writing on an approved form, by omitting the words “in writing”.

**Item 2** inserts a new subsection 37(3) to allow or require an application or information lodged by a manufacturer, to be given in accordance with specified software requirements, on a specified data processing device or by a specified kind of electronic transmission.

## Concluding comments

According to the government, the amendments proposed in the Bill are expected to facilitate the speedy submission of licence applications from manufacturers and the efficient handling of these applications by the TGA.<sup>15</sup> The amendments address the audit report recommendations that the TGA improve the integration of its information management systems, and strengthen its documentation procedures. However, in light of the Deloitte’s report, Parliament may want to confirm that implementation of all the ANAO’s recommendations has materially progressed since June 2005.

## Endnotes

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1. ‘[Good Manufacturing practice for therapeutic goods](http://www.tga.gov.au/docs/html/webgmp.htm)’. It is an offence, carrying heavy penalties, to manufacture therapeutic goods for human use without a licence unless the manufacturer or goods are exempt from this requirement. TGA website: <http://www.tga.gov.au/docs/html/webgmp.htm> accessed 5 June 2006. Products exempt from manufacturer licensing are listed in Schedule 7 of the Therapeutic Goods Regulations and similarly persons exempt from licensing are listed in Schedule 8.
2. ‘[Regulation of therapeutic goods in Australia](http://www.tga.gov.au/docs/html/tga/tgaginfo.htm)’. TGA website: <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm> accessed 5 June 2006.
3. Australia has Codes of GMP and Quality System requirements for the manufacture of medicinal products, sunscreen products, human blood and tissues, active pharmaceutical ingredients and medical devices. See ‘[Good Manufacturing practice for therapeutic goods](http://www.tga.gov.au/docs/html/webgmp.htm)’, TGA website: <http://www.tga.gov.au/docs/html/webgmp.htm> accessed 5 June 2006.

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4. Examples of where the Act already allows for the electronic lodgement of information include, among others, provisions contained in paragraphs 8 (1A), 23 (3), 26BA, 31 (3), 31A (4), 31B (5), 41JB (2), and 41JD (4).
5. 'Manufacturer information system', *TGA News* issue 45, November 2004, p.1, URL: <http://www.tga.gov.au/docs/html/tganews/news45/cover.htm#mis> accessed 5 June 2006.
6. Department of Health and Ageing, *Annual Report 2003-04*, Canberra, The Department, 2004, p. 87.
7. 'Manufacturer information system', op. cit.
8. Hon. Christopher Pyne, *Therapeutic Goods Amendment Bill (No. 3) 2006*, Second Reading Speech, House of Representatives *Hansard*, 11 May 2006, p. 7.
9. *ibid.*
10. Australian National Audit Office, *Regulation of Non-prescription medicinal products : Department of Health and Ageing, Therapeutic Goods Administration* Audit Report no. 18, 2004-05 Performance Audit, ANAO, December 2004.
11. *ibid.*, in particular, see audit Recommendation No. 23 and Recommendation No. 24, pp 119-120.
12. *ibid.*, p. 153.
13. Department of Health and Ageing, *Annual Report 2004-05*, op. cit, p. 62.
14. Deloitte, *Therapeutic Goods Administration: consultancy findings* prepared for the Department of Health and Ageing, June 2005, p 27. The report was issued in June but not made public until December 2005. See Lisa Allen, 'Deloitte tells TGA to improve procedures' *Australian Financial Review*, 8 December 2005, p. 7.
15. Hon. Christopher Pyne, op.cit.

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