



## Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009

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## Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009

**Date introduced:** 25 November 2009

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** Formal provisions: on Royal Assent

Schedule 1: a day fixed by Proclamation

Schedules 2–6: the day after Royal Assent

**Links:** The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

### Purpose

The primary purpose of the Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 (the Bill) is to introduce a framework for the regulation of biologicals, which is consistent with the regulation of therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act).<sup>1</sup> In addition, the Bill proposes other amendments to the Act, many of which are largely administrative in nature.

### Background

This Bill is part of the overall regulatory reform to the Act undertaken by the Therapeutic Goods Administration (TGA). Most of these reforms were agreed in the context of the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). Although the New Zealand Government ultimately decided to not proceed with the ANZTPA, the Australian Government decided to implement the proposed changes. This is the fourth Bill to be considered by Parliament. The passage of the previous three Bills has been largely uncontroversial.

Previously, the regulation of biologicals in Australia was not consistent with other regulators around the world such as the United States, Canada and the European Union. Biologicals are cellular and tissue based therapy products, for example, skin tissue for use in grafts. It is important to note that organs and assistive reproductive issues will not be

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1. For the proposed legal definition of ‘biologicals’, see Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 1, item 25—proposed section 32A** (see below at p. 6).

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affected by the proposed amendments and the current regulatory arrangements for these products will remain.<sup>2</sup>

The proposed amendments are designed to ensure that the regulation of biologicals is consistent with the regulation of other therapeutic goods. A risk based approach has been adopted and different levels of pre and post market regulation are applied based on the relative risk of each biological. The amendments will set out the classes of biologicals from low to high risk. Consistent with a risk based approach, higher risk biologicals will be subject to greater regulation. In addition, the criminal offence and civil penalty provisions are consistent with the provisions for other therapeutic goods.

In addition, a flexible approach has been built into the legislation when dealing with urgent medical circumstances. For example, biologicals which do not meet the legislative requirements but are considered clinically appropriate would be able to be used in treatment, with the consent of the patient.

To facilitate the implementation of the new regulatory framework for biologicals, the legislation provides for delayed implementation. This will enable further consultation with industry and finalisation of product-specific standards.

The Bill also contains the following proposed amendments:

- **Schedule 2** provides immunity to the Minister, Secretary and the Secretary's delegate from civil action, providing they did not act in bad faith. This is consistent with other Commonwealth legislation and other regulatory agencies
- **Schedule 3** allows for a more targeted approach to product recalls. Currently, the legislation does not allow for a recall of batches to occur. This can be excessive and expensive where only small numbers of batches are affected. The proposed amendments will enable specific batches to be recalled
- **Schedule 4** gives the TGA power to seek information from persons who have previously registered goods on the Australian Register of Therapeutic Goods (the Register)
- **Schedule 5** ensures that any unpaid charges are considered to be a debt owed to the Commonwealth and able to be recovered

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2. See Therapeutic Goods Authority, 'Exemptions from ARTG inclusion', *Biologicals framework implementation*, viewed 15 January 2010, <http://www.tga.gov.au/bt/hct.htm#exempt>

See also the proposed provisions in the Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 relating to exemptions for special and experimental uses (**Schedule 1, item 25—proposed sections 32CK and 32CL**), as well as for medical practitioners supplying specific biologicals for use in treating people (**Schedule 1, item 25—proposed section 32CM**).

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- **Schedule 6** is a series of administrative amendments. For example, improvements to post-marketing surveillance and clarification of what new information can be provided in the context of a merits review.

### Committee consideration

This Bill was introduced into the House of Representatives and read a second time on 25 November 2009. This was the second last day of the Parliamentary sitting for 2009, and as such, a decision on referral to a Committee has not yet been made.

### Stakeholder commentary

With respect to the proposed regulatory framework for biologicals, the Minister's Second Reading Speech notes that:

... the government has undertaken extensive consultation with the industry over the past year, including explaining the proposed framework to sponsors and manufacturers and setting out the steps they will need to take to comply with the framework.<sup>3</sup>

There does not appear to be any publicly available information about the nature of this consultation process and what information was provided. The 'regulatory reform' section on the TGA's website<sup>4</sup> only has information about the consultation sessions that were conducted in July/August 2008 and does not include the regulation of biologicals. The only information provided on this Bill on the TGA website is summary in nature.

Furthermore, there does not appear to be any stakeholder or media commentary on this Bill or its introduction.

### Main provisions

As previously mentioned, there are six Schedules in the Bill, which deal with matters including:

- a new separate framework for dealing with biologicals
- immunity of the Commonwealth and certain people acting for the Commonwealth from civil and criminal actions

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3. M Butler MP (Parliamentary Secretary for Health), 'Second Reading Speech, Therapeutic Goods Amendment (2009 Measures No. 3)', House of Representatives, *Debates*, 25 November 2009, p. 12797.

4. See <http://www.tga.gov.au/regreform/index.htm>

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- recall of therapeutic goods without suspension or cancellation of the listing of the therapeutic goods in the Register
- gathering information from previous sponsors of therapeutic goods
- classifying annual charges as debts due to the Commonwealth and recoverable as such
- advertising statements, and
- review of decisions and remittance of matters for reconsideration.

## Schedule 1

As mentioned previously, **Schedule 1** of the Bill provides for biologicals to be regulated separately from other therapeutic goods and medical devices.

### What are ‘biologicals’?

**Item 25** proposes to insert a **new Part 3-2A** into the Act, specifically related to the regulation of biologicals.

**Proposed section 32A** provides that ‘biological’ means something which:

- either comprises, contains or derives from human cells or tissues; or is specified as such by the Secretary by legislative instrument under **proposed subsection 32A(2)**, and
- is either represented to be; or—because of how it is represented or for any other reason—is likely to be taken as being for use in:
  - treating or preventing a disease, ailment, defect or injury affecting a person
  - medically diagnosing a person’s condition
  - influencing, inhibiting or modifying a physiological process in people
  - testing people’s susceptibility to a disease or ailment, or
  - replacing or modifying parts of people’s anatomies.

The Secretary may also specify, by legislative instrument, that something is not a biological (**proposed subsection 32A(3)**).

**Proposed section 32AA** provides that the regulations may prescribe different classes of biologicals. According to the Government:

This reflects the policy intent that regulation of these goods is correlated to the relative risk of each biological, that is, biologicals of a lower risk level would be subject to less rigorous evaluation and regulation compared with higher risk

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biologicals. It is expected that the regulations will specify four classes of biologicals ranging from lower risk (Class 1) to higher risk (Class 4).<sup>5</sup>

### **Criminal offences and civil penalties**

There is a tiered criminal offence regime, as well as civil penalties, proposed in relation to dealing with biologicals, which are set out in **proposed Division 2** of **Part 3-2A**, as well as in other parts of the Bill.<sup>6</sup> So the more serious offences resulting in, or likely to cause, harm or injury would attract heavier sanctions. It is stated in the Explanatory Memorandum that:

There is a tiered offence regime for a number of criminal offences, encompassing higher level penalties within a structure that usually includes:

- a fault-based offence with an aggravating element (conduct that results or will result in harm or injury to a person or persons), generally attracting a maximum penalty of 4,000 penalty units (presently \$440,000) or 5 years imprisonment or both;
- a strict liability offence with an aggravating element (conduct likely to result in harm or injury to a person or persons), generally attracting a maximum penalty of 2,000 penalty units (presently \$220,000) with no term of imprisonment; and
- a fault-based offence, with no aggravating element, generally attracting a maximum penalty of 1,000 penalty units (presently \$110,000) or imprisonment for 12 months or both.<sup>7</sup>

It is noted that the Bill proposes certain strict liability offences in relation to the import, export, manufacture or supply, by a person, of biologicals not included in the Register in relation to that person, for potentially harmful use in humans.<sup>8</sup>

The Government explains that:

The strict liability offences are necessary and appropriate in maintaining the integrity of the regulatory scheme to ensure the safety, quality, and efficacy or performance of therapeutic goods supplied in Australia or exported from Australia.

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5. Explanatory Memorandum, Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009, p. 31.
  6. See, for example, Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 1, item 25—proposed sections 32CJ and 32CN; proposed Subdivision E of Division 4.**
  7. Explanatory Memorandum, op. cit., p. 32.
  8. See Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 1, item 25—proposed subsections 32BA(3), 32BB(3), 32BC(3) and 32BD(3).**

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The inclusion of strict liability offences takes into consideration statements made in the Senate Standing Committee for the Scrutiny of Bills Sixth Report of 2002 titled *Application of Absolute and Strict Liability Offences in Commonwealth Legislation*, and the *Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers* (the Guide), issued by authority of the Minister for Home Affairs in December 2007.

According to the above Guides, ‘*strict liability may be appropriate where it is necessary to ensure the integrity of a regulatory regime such as, for instance, those relating to public health, the environment, or financial or corporate regulation*’.

The strict liability offences proposed in the Bill are considered to be similar in application to the strict liability offences existing elsewhere in the Act.

They form an integral part of the full suite of alternative sanctions proposed for biologicals in relation to breaches of key regulatory requirements that will underpin the regulatory arrangements for biologicals. This is to protect public health and safety in respect of biologicals in a manner that is consistent with the existing schemes applying to medicines, therapeutic devices and medical devices, as currently set out in the Act.<sup>9</sup>

In addition, it is stated that the main criminal offence provisions and penalty levels are consistent with other provisions in the Act (please refer to the Appendix to this Digest).<sup>10</sup>

## Exemptions

There are four types of exemptions from the TGA’s regulatory framework relating to biologicals proposed in the Bill:

- exemptions under regulations (**proposed section 32CA**)
- exemptions to deal with potential and actual emergencies (**proposed section 32CB**)
- exemptions for special and experimental uses (**proposed sections 32CK-32CN**), and
- exemptions where substitutes are not available (**proposed section 32CO**).

It is noted that exemptions may be subject to conditions (**proposed subsections 32CA(3), 32CK(6)–(8) and 32CO(7); proposed sections 32CC and 32CL**) and that conditions relating to exemptions for biologicals in emergency situations may be varied or revoked (**proposed subsections 32CD(3)**).

In all cases, a breach of these conditions constitutes an offence with varying penalty units (for example, **proposed subsections 32CA(4), 32CK(9), 32CL(2), 32CO(8)** and

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9. Explanatory Memorandum, op. cit., pp. 34–35.

10. Ibid., pp. 33 (criminal), 35–37 (civil).

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**proposed section 32CI**), and in some cases, tiered terms of imprisonment (for example, **proposed sections 32CH** and **32CN**).

### **Non-conformity to standards**

There are also criminal offences and civil penalties relating to situations where biologicals do not conform to applicable standards or are otherwise unfit to be used for their intended purpose (**proposed subsections 32CJ(6)–(11)**). Where a person supplies a batch of biologicals and the Secretary is satisfied that biologicals in that batch do not conform to applicable standards or are otherwise unfit to be used for their intended purpose, the Secretary has discretionary power to require that person, by written notice, to take steps to recover such biologicals—unless the biologicals have been administered to or used in treating a person and consequently, cannot be recovered. Failure to comply with that requirement would constitute a criminal offence or civil contravention, depending on the circumstances and consequences of such failure to comply.

### **Including biologicals in the Register**

Application and assessment procedures relating to biologicals would be different for Class 1 biologicals considered to be of low risk and other classes of biologicals with increasing levels of risk.<sup>11</sup>

#### Class 1 biologicals

Under **proposed subsection 32DB(1)**, the Secretary must include the Class 1 biological in the Register, in relation to a particular person, if that person makes an application to include the Class 1 biological in the Register in accordance with **proposed section 32DA**. Under **proposed subsections 32DA(2)** and **(3)**, an application must be accompanied by a statement from the applicant in which the applicant must certify several things about the Class 1 biological including that the biological:

- is in fact a Class 1 biological and is safe for its intended use
- conforms to applicable standards
- complies with applicable advertising requirements; as well as prescribed quality and safety criteria (if any), and

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11. For an explanation of the different classes of biologicals proposed in the Bill, see *ibid.*, pp. 12–13. See also Therapeutic Goods Authority, ‘Classification of biological products’ and ‘Levels of regulation to be applied to each class’, *Biological framework implementation*, viewed 15 January 2010, <http://www.tga.gov.au/bt/hct.htm>

See also Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 1, item 25—proposed section 32AA**.

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- does not contain any substances that are prohibited imports under the *Customs Act 1901*.

#### Other biologicals

Under **proposed subsection 32DE(1)**, where an application is made to include a biological other than a Class 1 biological in the Register, the Secretary must evaluate the biological with regard to matters including:

- satisfactory establishment of the biological's quality, safety and efficacy in relation to its intended use
- acceptability of the biological's presentation, as well as of the quality control and manufacturing procedures followed in its manufacture
- the biological's conformity with applicable standards
- the biological's compliance with applicable advertising requirements, and
- whether the biological contains any substances prohibited under the *Customs Act 1901*.

**Proposed sections 32DI–32DM** set out provisions relating to an evaluation fee, which is payable for evaluation of the non-Class 1 biological and may be recovered by the Commonwealth as a debt due to it. Such a fee would be specified in the regulations or its method of calculation would be prescribed in the regulations. The amount may be reduced if the evaluation is incomplete within a prescribed period of time.

#### Refusal of applications

Note that where the Secretary refuses an application to include a biological in the Register, the Secretary must give the person notice of the refusal and reasons thereof as soon as practicable (**proposed sections 32DC and 32DG**).

#### Criminal offences and civil penalties

As mentioned above, the Bill proposes a tiered regime of criminal offences and civil penalties, which are consistent with other parts of the Act, in relation to:

- false statements made in applications to include biologicals in the Register (**proposed section 32DO**), and
- failure to notify various matters, such as adverse effects of a biological, while it is included in the Register or where the application is withdrawn or lapses (**proposed sections 32DQ and 32DR**).

It is noted that, under **proposed subsection 32DR(1)**, where an application to have a biological included in the Register is withdrawn or lapses, the Secretary would have

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discretionary power to give the applicant written notice—within 14 days of the application being withdrawn or lapsing—requiring the applicant to:

- inform the Secretary of whether he or she knows of information specified in **proposed subsection 32DR(2)**, and
- if so, to give such information to the Secretary.

However, given the 14 day time limit in particular, it is unlikely that this requirement would pose an unreasonably heavy onus on such applicants.

#### Consultation with Gene Technology Regulator

**Proposed sections 32DS–32DU** enable the Secretary to consult with the Gene Technology Regulator when an application is made for inclusion of a biological in the Register and the biological is or contains a genetically modified product or organism. If the Gene Technology Regulator’s advice has been sought and received under the relevant provision, the Secretary must consider such advice in making a decision about the application.

#### Conditions on inclusion of biologicals in the Register

**Proposed Division 5** sets out provisions relating to various types of conditions that would apply to biologicals included in the Register under **proposed Part 3-2A**.<sup>12</sup> Some conditions would apply automatically and others would be imposed by a legislative instrument made by the Minister. In order to prevent imminent risk of death, serious illness or injury, additional conditions can also be imposed at or after the time the biological is included in the Register. Those conditions may also be varied or removed from the Register either at the request of the Secretary or the person concerned (**proposed sections 32ED** and **32EE** respectively).

A breach of a condition would constitute an offence/contravention, incurring either criminal penalties/imprisonment or civil penalties, depending on the circumstances such as the seriousness/likelihood of harm to people resulting from the breach (**proposed sections 32EF** and **32EG**).

#### Automatic conditions

There are certain conditions that apply automatically to the inclusion of a biological in the Register, as set out in **proposed section 32EA**:

- entry and inspection powers
- delivery of samples

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12. Part 3–2A sets out the main provisions relating to the new regulatory framework of biologicals.

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- specific information with respect to the manufacture of the biological
- expiry date, and
- advertising the biological only for accepted indications.

#### Conditions by legislative instrument

The Minister may, by legislative instrument, impose conditions that relate to matters including:

- manufacture of the biological
- custody, use, supply, disposal and destruction of the biological, and
- record keeping.

It is noted that different conditions may be imposed on different classes of biologicals, for example:

... different record keeping requirements may be applied under this section where additional tests are required to be undertaken on a class of biologicals, as prescribed by the standard applicable to that class of biologicals (section 10 of the Act refers).<sup>13</sup>

#### Suspension from the Register

The Secretary has discretionary power to suspend a biological from the Register in particular circumstances, including:

- if the Secretary is satisfied that:
  - there is a potential risk of death; or serious illness or injury, if the biological remained in the Register, and
  - during the time of suspension, it is likely that the person (in relation to whom the biological is included in the Register) will be able to take necessary action to prevent such potential risk, or
- if the Secretary is satisfied that there are likely grounds for cancelling the entry of the biological in the Register under **proposed Division 7**.

However, before suspending a biological, the Secretary must provide that person with written notice about the proposal to suspend, setting out reasons for the proposed suspension and inviting the person to make written submissions regarding the suspension within a specific period of time (no less than 28 days after the day the notice is given). The Secretary cannot make any decision about the suspension without considering such submissions.

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13. Explanatory Memorandum, op. cit., p. 71.

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The Secretary must revoke a suspension if he or she is satisfied that the reason for which the biological was suspended from the Register no longer applies and there are no other grounds for its suspension (**proposed subsection 32FC(1)**).

Suspension of a biological from the Register would have the effect of the biological being taken to generally not be included in the Register for the purposes of the Act.<sup>14</sup> It is noted that dealing in a biological that is not included in the Register may be a criminal offence or civil penalty contravention under **proposed Division 2 (Main criminal offences and civil penalties)**.

### **Cancellation from the Register**

Under **proposed Division 7**, the Secretary may immediately cancel the entry of biologicals in the Register in particular circumstances. These include where:

- the Secretary is satisfied there would be imminent risk of death, serious illness or serious injury if the biological remains in the Register
- the biological either stops being a biological or is declared by order under section 7 of the Act not to be therapeutic goods
- the person requests the cancellation in writing (see also **proposed section 32GD**)
- the biological contains substances that are prohibited imports under the *Customs Act 1901*
- the Secretary is satisfied that a statement made in connection with the application to include the biological in the Register was false or misleading in a material particular
- there has been failure to comply with conditions relating to entry and inspection of premises or to deliver relevant samples, or
- there has been a breach of advertising requirements (**proposed section 32GA**).

It is noted that in such circumstances:

The Secretary is not required to give the person who is adversely affected by the decision (the person who is given a notice of the decision), a prior opportunity to respond to the cancellation. This is because the circumstances set out in subsection (1) are either very serious and require an immediate response to prevent or reduce the risk to public health or are such that inclusion in the Register is no longer appropriate or necessary.<sup>15</sup>

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14. Except, however, in relation to Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 1, item 25—proposed sections 32DQ, 32FB and 32FC; proposed Divisions 5, 7 and 9**. See also **proposed subsection 32FD(1)**.
  15. Explanatory Memorandum, op. cit., p. 76.

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The Secretary may also immediately cancel the entry of a biological in the Register due to a failure to comply with an information gathering notice under **proposed section 32JA** within a particular period of time (**proposed section 32GB**).

Under **proposed section 32GC**, the Secretary also has discretionary power to cancel an entry of a biological in the Register, after notice is given of the proposed cancellation, in various circumstances including where:

- it appears to the Secretary that the quality, safety, efficacy or presentation of the biological is not acceptable
- the biological has changed to the extent that it has become separate and distinct from that which was included in the Register
- the person has breached conditions to which the inclusion of the biological was subject (apart from conditions under **proposed subsection 32EA(1)** or **(3)**)
- the person contravenes **proposed subsection 32DQ(1)** or **(2)** by failing to notify of adverse effects of the biological while it is included in the Register, or
- the biological does not conform to an applicable standard.

In such circumstances, before cancelling the entry of the biological in the Register, the Secretary must, in writing, notify the person that the Secretary proposes the cancellation, set out the reasons for the proposed cancellation and invite the person to make submissions about it within a specified period of time (not less than 28 days after the day the notice was given). It is noted that the Secretary cannot make a final decision without considering those submissions.

Importantly, it is noted that decisions to cancel an entry of a biological in the Register are initial decisions and are consequently reviewable under the Act.<sup>16</sup>

### **Public notification and recovery of biological**

Under **proposed subsection 32HA**, the Secretary may require certain people in certain circumstances to recover biologicals or to inform the public about biologicals that do not comply with requirements or that have not been lawfully supplied.

Failure to comply with such requirements may constitute a criminal offence or a contravention of a civil penalty under **proposed sections 32HC** and **32HD** respectively.

The Explanatory Memorandum states that a decision made under **proposed section 32HA** would also be a reviewable decision under the Act.<sup>17</sup>

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16. Ibid.

17. Ibid., p. 79.

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### Obtaining information or documents

Under **proposed section 32JA**, the Secretary may, by written notice, request certain information or documents where:

- an application has been made to include a biological in the Register
- the biological is already in the Register, or
- the person (applying to have the biological included in the Register) is someone in relation to whom the biological had been, at any time during the preceding five years, included in the Register.

There is a tiered regime of criminal offences for failure to comply with such a notice and for giving false and misleading information under **proposed section 32JB**.

Provision of false and misleading information may also result in a civil penalty under **proposed section 32JC**.

Importantly, it is noted that **proposed section 32JD** provides that a person cannot rely on the right to avoid self-incrimination to avoid complying with such requirements. However, where information relates to an individual, that person is protected as information obtained is inadmissible as evidence against that person, except in certain proceedings for offences such as failing to comply with a notice etc (**proposed subsections 32JB(1)–(3) and (5)**); and proceedings under section 42Y for contravention of provisions relating to providing false and misleading information (**proposed section 32JC**). It is stated in the Explanatory Memorandum that:

This provision is necessary to ensure compliance with the necessary requirements and the monitoring of biologicals that will be supplied to the public or have been supplied to the public. It is important the Secretary is able to request and obtain the necessary safety, quality and safety information about biologicals and that the relevant person requested to provide the information complies with the request. The receipt of this information about the biologicals will enable the Secretary to make informed and timely decisions about biologicals that adversely affect public health and safety.<sup>18</sup>

The Secretary may, by written notice, also require certain information or documents about biologicals exempt under the regulations (**proposed section 32JE**) and biologicals exempt to deal with emergencies (**proposed section 32JF**). Such information or documents would relate to one or more of the following:

- the supply of the biological
- the handling of the biological
- monitoring of the supply of the biological

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18. Ibid., p. 82.

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- results of the supply of the biological, and
- any other matter prescribed in the regulations for these purposes.

The Secretary may, by written notice, also require similar information or documents about biologicals that are exempt for special or experimental uses from people approved or authorised to import, export or supply such biologicals (see **proposed subsections 32JG(1) and (3)**). However, a request for information can also be made to an experimenter using a biological subject to approval held by another person and covering the importation into, or supply in, Australia of the biological only for experimental use in people (**proposed subsections 32JG(2)**).

Under **proposed section 32JH**, the Secretary may require information or documents about biologicals exempted because substitutes are not available or are in short supply and the biologicals are necessary for public health interests.

Note that **proposed subsection 32JI(1)** sets out criminal offences for failing to comply with such notices. Giving false and misleading information or documents would constitute either a criminal offence or a civil contravention under **proposed subsection 32JI(2)** and **proposed section 32JJ** respectively.

**Proposed section 32JK** has a similar effect as **proposed section 32JD** with respect to self-incrimination (see above).

### Miscellaneous amendments relating to biologicals

**Item 26** proposes to insert **new section 33B** into the Act, providing that Part 3-3 of the Act would not apply to Class 1 biologicals. According to the Government:

This is because Class 1 biologicals will have a low risk level and have minimal manufacturing involved in their production. This also means that manufacturers of class 1 biologicals will not be required to hold a manufacturing licence.<sup>19</sup>

**Items 27–29** propose to amend **paragraphs 35(1)(a), 35(2)(a), 35(4)(a), 35(5)(c), 35(7)(c), 35(9)(c), 35A(1)(c) and 35A(2)(c)**, effectively exempting biologicals, already exempt for the purposes of dealing with emergencies, from the respective criminal offences and civil penalty provisions in those paragraphs. Those offences and penalties relate to the manufacturing of therapeutic goods and are consistent with how they apply to other therapeutic goods exempted the purposes of dealing with emergencies under section 18A.

**Item 31** proposes to substitute **paragraph 40(4)(a)** in the Act. Section 40 relates to conditions that may be placed on manufacturing licences of therapeutic goods. **Proposed subparagraphs 40(4)(a)(i) and (ii)** provide that in addition to any condition imposed on a

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19. Ibid., p. 86.

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manufacturing licence under subsections 40(1) and (2), the licensee may also be subject to a condition that the therapeutic goods conform to applicable standards and the licensee observes the manufacturing principles when carrying out steps in the manufacturing process. However, under **proposed subparagraphs 40(4)(a)(iii)** and **(iv)**, this would not apply to biologicals for supply in circumstances prescribed by the regulations:

... because under exceptional release the biologicals may not meet the applicable standards for the biologicals or their manufacture ...<sup>20</sup>

Importantly, **item 49** proposes to amend **subsection 60(1)** of the Act, so as to include decisions made under **proposed Part 3-2A (Biologicals)** in the definition of ‘initial decision’ that would be reviewable under the Act.

## Schedule 2

**Schedule 2** contains proposed amendments relating to immunity from civil actions generally under the Act.

**Item 14** proposes to insert **new section 61A** into the Act, which would provide that the Commonwealth and ‘protected persons’ would be immune from civil actions, suits and proceedings, for any loss, damage or injury resulting from anything done (or omitted to be done) by a protected person in relation to the performance or exercise of a protected person’s functions, duties or powers under the Act or regulations.<sup>21</sup> Omissions would include a failure to make a decision.

It is noted that there would be no immunity for anything done in bad faith.

Currently, the Act does contain several provisions conferring similar immunity. However, these provisions differ in terms of the breadth of immunity conferred and to whom such immunity is conferred.<sup>22</sup>

## Schedule 3

**Schedule 3** contains proposed amendments to enable recall of therapeutic goods or a medical device, where the Secretary believes either that the quality, safety or efficacy of the goods/device or that the presentation of the goods/device is unacceptable.

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20. Ibid., p. 87.

21. As to the meaning of ‘protected person’, see Therapeutic Goods Administration (2009 Measures No. 3) Bill 2009 **Schedule 2, item 14—proposed subsection 61A(4)**.

22. See Explanatory Memorandum, op. cit., p. 94.

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Currently, the Act only enables the Secretary to recall in other specific circumstances, without being able to do so for unacceptable quality, safety or efficacy of the goods/device or presentation of the goods/device.<sup>23</sup>

## Schedule 4

**Schedule 4** sets out proposed amendments to section 31 of the Act, relating to information gathering.

The amendments proposed in **items 1–5** would enable the Secretary to request information from people who used to be persons in relation to whom therapeutic goods were included in the Register but who no longer are in that category of people. Currently, section 31 does not allow for this to happen. It is stated in the Explanatory Memorandum that:

A sponsor of therapeutic goods may decide to seek the cancellation of registered or listed goods in relation to that sponsor as there may be some safety or quality issues in relation to those goods. Without the additional power to require sponsors of cancelled goods to provide relevant information or documents, the Secretary could be impeded in obtaining information as part of an investigation into a safety issue if, for example, a person who was responsible for a registered or listed product had relinquished that responsibility before the investigation began. These amendments extend the Secretary's power to obtain information to such persons for a period of five years.<sup>24</sup>

This could be regarded as being relevant to regulating biologicals under Schedule 1 of the Bill, as a former registrant could be required to give certain information under **proposed sections 32DQ** and **32DR**.

## Schedule 5

**Schedule 5** contains provisions relating to unpaid annual charges.

Under the Act, annual charges are payable with respect to the registration, listing or inclusion of therapeutic goods in the Register, as well as manufacturing licences issued under the Act.

Part 6–1 of Chapter 6 of the Act deals with payment of charges. **Item 1** proposes to **insert new section 44B** into the Act, providing that unpaid amounts of:

- annual registration charges
- annual listing charges
- annual charges for inclusion in the Register, and

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23. Ibid., p. 97.

24. Ibid., p. 98.

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- annual licensing charges

are recoverable as debts due to the Commonwealth if such amounts are unpaid at the end of a 28 day period of time commencing after the day on which such a charge becomes payable.<sup>25</sup>

## Schedule 6

**Schedule 6** contains provisions proposing various amendments to the Act.

It is noted that **items 8–18** propose to **amend section 60A**, relating to when the Minister (in reconsidering an initial decision) or the Administrative Appeals Tribunal (in reviewing the Minister’s reconsideration of an initial decision) may consider additional information supplied by the applicant.

It is stated in the Explanatory Memorandum that:

The policy intent of these amendments is that if new information is provided to the Minister or the AAT, those decision-makers should be able to remit the decision and the additional information for consideration by the Secretary (or her delegate), unless the additional information indicates that the quality, safety or efficacy of the goods in unacceptable.

...

However, the way the current provisions operate means that in some circumstances this may not be possible.

The amendments are intended to rectify this, mainly by drawing a distinction between initial new information (relevant information in existence at the time of the initial decision but not made available to the Secretary or her delegate) and later new information (relevant information in existence at the time of Ministerial reconsideration but not made available to the Minister).<sup>26</sup>

**Item 19** proposes to repeal the existing definition of ‘new information’ in **subsection 60A(8)**. Under the existing definition, ‘new information’ is information that:

- existed at the time the decision was made under sections 25 and 41EC
- was not made available to the Secretary or authorised delegate for the purpose of making that decision
- is relevant to the decision, and

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25. As to when such a charge becomes payable, see *Therapeutic Goods Act 1989* section 44.

26. Explanatory Memorandum, op. cit., pp. 103–104.

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- includes opinions that are completely or substantially based on such information, irrespective of whether those opinions were formed before the decision was made.

**Item 17** proposes to amend **subsection 60A(8)** by inserting a new definition of ‘initial new information’, which essentially reflects the existing meaning of ‘new information’ in the Act.

**Item 18** proposes to amend **subsection 60A(8)** by inserting a new definition of ‘later new information’. ‘Later new information’ would mean information that:

- existed at the time the decision on reconsideration was made
- was not made available to the Minister or the Minister’s delegate for the purpose of making that decision, and
- is relevant to the decision.

This would also include opinions that are completely or substantially based on such information, irrespective of whether those opinions were formed before the decision was made.

**Item 16** also proposes to amend the definition of ‘authorised delegate’ in **subsection 60A(8)**, by adding to the functions of an authorised delegate. The new function would require the delegate to exercise a power to decide whether to issue a conformity certificate.

**Item 10** proposes to substitute **subsection 60A(4)** so that if:

- the appellant applies to the Administrative Appeals Tribunal (AAT) for a review of a decision on reconsideration, lodging ‘initial new information’ in support of the application, and
- the appellant fails to lodge ‘later new information’ in support of the application,

the AAT must not remit the matter under subsection 60A(3) if all of the initial new information was considered by the Minister in making his or her decision on reconsideration.<sup>27</sup>

It is stated in the Explanatory Memorandum that:

This is because the Minister has been given the opportunity to consider the initial new information in the reconsideration of the initial decision and no additional later new information is lodged which the Minister may not have had the opportunity to consider.<sup>28</sup>

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27. In relation to court proceedings and appeals, ‘to remit a matter’ generally refers to the appellate court sending back the proceedings to the court of original jurisdiction for further consideration and action.

28. Explanatory Memorandum, op. cit., p. 104.

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**Items 11–14** propose to amend **subsection 60A(5)** so that the AAT would be able to consider initial new information already considered by the Minister on reconsideration, but would not be able to consider any other ‘new initial information’ or ‘later new information’ unless it is information indicating that the quality, safety and efficacy of the therapeutic goods are unacceptable.

This arrangement is designed to ensure that all the relevant information is first put to the Minister for his or her consideration before the matter is heard by the AAT on appeal.

### **Concluding comments**

In the absence of any wider commentary, it is difficult to make an assessment of the proposed amendments. However, the planned changes for the regulation of biologicals seek to align Australia’s regulatory framework with other international regulatory agencies such as the US, Canada and Europe. This will ensure that Australia’s regulatory framework remains consistent with those of other pharmaceutical regulatory agencies and is also part of the broader regulatory reform program currently being implemented by the TGA. It appears that the proposed administrative amendments will enhance the regulation of therapeutic goods in Australia.

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## Appendix

### TGA criminal offence provisions

<b>Proposed new provision</b>	<b>Offence</b>	<b>Provision(s) in the Act upon which provision based</b>
Sections 32BA to 32BD	Importation, exportation, manufacture or supply of unassessed or unapproved biologicals	Section 19B
Section 32BI	Using a biological in the treatment of another person or solely for experimental purposes, in circumstances where the biological has not been approved or assessed or specifically exempted or approved for that purpose	Subsections 21A(12) to (14) and subsection 22(8)
Section 32CH	Breaching a condition attaching to the exemption of a biological from the requirement to be included in the Register	Subsections 22(7AB) to (7A)
Subsections 32CJ(6)-(10)	Supplying a biological that does not conform with an applicable standard	Section 30F
Section 32CN	Supplying a biological authorised by the Secretary under subsection 32CM(1) in a manner other than in accordance with that authority	Subsections 21A(9) to (11) and subsection 22(7A)
Section 32DO	Making a false or misleading statement in an application for inclusion of a biological in the Register	Section 22A
Section 32EF	Breaching a condition attaching to the inclusion of a biological in	Subsections 21A(5) to (8)

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	the Register	
Section 32HC	Non-compliance with a requirement in relation to public notification and recovery of biologicals	Section 30EC
Subsections 32JB(2)-(5)	Providing information or documentation to the Secretary in purported compliance with a notice issued by the Secretary if the information or documentation provided is false or misleading in a material particular	Subsections 31(5A) to (6)

## TGA civil penalty provisions

<b>Civil penalty provision</b>	<b>Relevant conduct to which provision relates</b>	<b>Maximum penalty</b>	<b>Corresponding criminal offence provision in the Bill</b>	<b>Provision in the Act upon which civil penalty provision based</b>
Subsections 32BF(1) – (5)	Importing into, exporting from, manufacturing in or supplying, in, Australia, biologicals not included in the Register or in relation to which, or the relevant person specified, exemptions, approvals or authorities do not apply	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Sections 32BA-32BD	Section 19D
Subsection 32BF(6)	Supplying a biological in Australia without the biological number on the label	200 penalty units for an individual 2,000 penalty units for a	N/A	Subsection 19D(4)

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		body corporate		
Subsection 32BG(2)	Importing into, exporting from, manufacturing in or supplying in, Australia, a biological if the sponsor has not notified the Secretary of the manufacturer or manufacturing premises	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Subsection 32BG(1)	Section 20A
Section 32BK	Making a representation about specified matters that is false or misleading	5,000 penalty units for an individual 50,000 penalty units for a body corporate	N/A	Subsection 21B(3)
Section 32CI	Breaching a condition of an exemption under proposed section 32CB in relation to a biological	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Section 32CH	Section 22AA
Subsection 32CJ(11)	Failing to comply with a requirement to recover substandard or unfit biologicals	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Subsections 32CJ(6), (7) and (9)	Section 30FA
Subsection 32DP	Making a false or misleading statement in or in connection with an application for inclusion in the Register	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Section 32DO	Section 22B

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Subsection 32DQ(2)	Failing to notify the Secretary of adverse effects of a biological	3,000 penalty units for an individual  30,000 penalty units for a body corporate	Subsection 32DQ(1)	Section 29AA
Subsection 32DR(5)	Failing to notify the Secretary, if required, of adverse effects of a biological after an application for inclusion of the biological in the Register lapses or is withdrawn	3,000 penalty units for an individual  30,000 penalty units for a body corporate	Subsection 32DR(3)	Subsection 29C(1)
Subsection 32DR(6)	Giving information to the Secretary on a lapsed or withdrawn application for inclusion of a biological that is false or misleading	3,000 penalty units for an individual  30,000 penalty units for a body corporate	Subsection 32DR(4)	Subsection 29C(2)
Subsection 32EG	Breaching a condition of inclusion of a biological in the Register	5,000 penalty units for an individual  50,000 penalty units for a body corporate	Subsection 32EF	Subsection 21B(2)
Section 32HD	Breaching a requirement relating to the public notification and recovery of biologicals under section 32HA	5,000 penalty units for an individual  50,000 penalty units for a body corporate	Section 32HC	Sections 30ECA and 41KCA
Section 32JC	Giving information to the Secretary on a range of	5,000 penalty units for an	Section 32JB	NA

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	matters such as formulation and design of a biological that is false or misleading	individual  50,000 penalty units for a body corporate		
Section 32JJ	Giving information to the Secretary on a biological exempt under the regulations, as it is required to deal with an emergency, because of unavailability, or for special and experimental purposes, that is false or misleading	5,000 penalty units for an individual  50,000 penalty units for a body corporate	Section 32JI(2)J	N/A

These tables may be found at Explanatory Memorandum, *op. cit.*, pp. 33 (criminal offences) and 35–37 (civil offences).

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