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THERAPEUTIC GOODS AMENDMENT (2009 MEASURES NO. 3) BILL 2009

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2009

EXPLANATORY MEMORANDUM

(Circulated by authority of the Hon Mark Butler MP, Parliamentary Secretary for Health)

Table of contents

OUTLINE

THERAPEUTIC GOODS AMENDMENT (2009 MEASURES NO. 3) BILL 2009

The Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009 (the Bill) makes a series of amendments to the *Therapeutic Goods Act 1989* (the Act). These include:

- introducing a new framework for the regulation of biological therapeutic goods;
- providing immunity from legal proceedings for individuals employed by or acting for the Commonwealth where they act in accordance with the Act;
- enabling greater flexibility for recall of therapeutic goods without requiring that the entry of the good in the Register be suspended or cancelled;
- empowering the Secretary to seek information from past sponsors of medicines and therapeutic devices in relation to the time that they were the sponsor (also provided for under Schedule 1 for biologicals);
- providing that unpaid annual charges are a debt due to the Commonwealth; and
- other minor amendments.

Schedule 1 – New framework for biologicals

At present human cellular and tissue based therapy products (known as biologicals) are regulated as either medicines or therapeutic devices under the Act. This is not ideal as it does not reflect the specific nature and production of these therapeutic products. Globally, there has been a move to regulation of these products separately from other therapeutic goods. As a result, this Bill will establish a new separate framework for the regulation of biologicals under new part 3-2A in the Act.

The key principles of therapeutic goods regulation, as applied to other therapeutic goods in Australia under the Act, will be maintained by the Bill for biologicals. Further, a new biologicals-specific exemption arrangement will be established to enable biologicals that would otherwise not conform to approved standards to be released in exceptional, life saving circumstances where no other conforming biological or approved therapeutic good is available or would be suitable.

Schedule 2 – Immunity from civil and criminal actions

Presently various provisions in the Act provide that legal proceedings may lie against the Commonwealth or a person acting in accordance with specific provisions in the Act. This Bill replaces those provisions with a new section to clarify that where the Commonwealth or a person who is acting for the Commonwealth (including the Minister, Secretary, authorised delegates, etc) undertakes actions in accordance with the Act they are immune from legal action in respect of that act.

Schedule 3 – Recall of therapeutic goods

Presently goods may be recalled following the suspension or cancellation of the listing for the goods in the Register. However, there are circumstances where only a specific batch or batches of the goods where there are concerns regarding the quality, safety, efficacy, presentation or performance and need to be recalled to prevent their use. This schedule will provide that in such circumstances the entry of the good in the Register does not need to be suspended or cancelled to enable the recall.

This provides a more flexible and targeted approach in such circumstances and enables the continued supply and use of unaffected batches so that access to the good is not interrupted unnecessarily.

Schedule 4 – Information gathering

While under the Act information may be sought from the current sponsor and manufacturer of a medicine or therapeutic device, there may be circumstances where information that is necessary to ensure safety and quality can only be provided by a person who was previously the sponsor of the good.

This Bill will provide that persons in relation to whom therapeutic goods were previously registered or listed (the sponsor) can be asked to provide information that relates to the period during which they were the sponsor over the five years prior to the information request. This is consistent with the information gathering provisions in relation to medical devices under the Act.

Schedule 5 – Unpaid annual charges

The Bill will clarify that unpaid annual charges are a debt due to the Commonwealth and may be recovered as such.

Schedule 6 – Other amendments

Other amendments will be made to the Act by this Bill. The most significant include:

- clarifying that statements in advertisements that would otherwise be prohibited under the Act do not constitute an offence where the government has are required that they be made;
- clarifying the types of information on the basis of which the Minister or Administrative Appeal Tribunal may remit a matter for reconsideration by the Secretary or her or his delegate so that this includes any information held by the applicant but not made available to the original-decision maker;
- clarifying the definition of ***therapeutic good*** to include goods that are declared to be therapeutic goods.

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2009

The Therapeutic Goods (Charges) Amendment Bill 2009 (the Charges Bill) makes a number of amendments to the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).
These are to:

- enable annual charges to be levied in respect of the inclusion of biologicals in the Register; and
- provide that where a registered or listed good (under Part 3-2 of the Act) or a biological (under Part 3-2A of the Act, to be inserted by the Therapeutic Goods Amendment (2009 Measures No.3) Bill 2009) is suspended from the Register under the Act that good can continue to be taken to be included in the Register for the purposes of the Charges Act.

FINANCIAL IMPACT STATEMENT

The amendments made by this Bill will have a nil financial impact on the Commonwealth as the Therapeutic Goods Administration, which administers the Act, operates on a cost recovery basis.

REGULATORY IMPACT STATEMENT - BIOLOGICALS

Glossary of terms and acronyms used in this statement

ANZTPA	Australia New Zealand Therapeutic Products Authority
ART	Assisted Reproductive Technology
ARTG	Australian Register for Therapeutic Goods
cGMP	current Code of Good Manufacturing Practice
CFR	Code of Federal Regulations
CTN	the Clinical Trial Notification Scheme (operated by the TGA)
CTX	the Clinical Trial Exemption Scheme (operated by the TGA)
FDA	(US) Food and Drug Administration
GHTF	Global Harmonization Task Force
HCT	Human Cell and Tissue Therapies (also referred to as 'biologicals')
RIS	Regulatory Impact Statement
RTAC	Reproductive Technology Accreditation Committee
SAS	Special Access Scheme (operated by the TGA)
TGA	Therapeutic Goods Administration
TG Act	*Therapeutic Goods Act 1989*
TG Regulations	Therapeutic Goods Regulations 1990
TSANZ	Transplantation Society of Australia and New Zealand

Background

In July 2002, the Australian Health Ministers Conference (AHMC) recommended that the Therapeutic Goods Administration (TGA) introduce a national regulatory framework for human tissues and emerging biological therapies.

Consistent with this recommendation, the TGA began developing a national regulatory framework for human cell and tissue therapies (HCTs) in consultation with stakeholders and within the context of the development of the Australia New Zealand Therapeutic Products Authority (ANZTPA). However, in July 2007 the development of the joint agency was suspended due to lack of support for the enabling bill in the New Zealand Parliament.

Although development of the joint agency is currently suspended, the amendments proposed under it remain necessary within an Australian regulatory context.

During the development of the joint agency a number of options for HCTs were considered and reflected in discussion papers and a draft Regulation Impact Statement (RIS). Comments on that draft RIS received from stakeholders were incorporated and the RIS was then approved by the then Office of Regulation Review in 2004 (ORR reference 5066).

This RIS amends that original version with updates on the current regulatory and biologicals (HCTs) environment and recent further consultations with stakeholders undertaken in 2008. The need to improve regulation of the growing therapeutics area of biologicals remains and this RIS considers options to achieve this in an Australia-only context.

What are human cell and tissue therapies (HCTs)?

In summary, tissue therapy involves the use of tissues as therapeutic goods, while cell therapy involves the use of isolated living cells either as therapeutic goods or as replacements for cells that are defective or deficient in particular disorders.

The distinction between cell therapy and tissue therapy may sometimes be blurred. A therapy may make use of living cells organised as tissues to grow or differentiate to treat a condition, or tissues may be purified to extract certain cells that may be used for therapeutic benefit.

Some examples of tissue therapies currently being used are:

- skin replacement after severe burns;
- transplantation of heart, kidney, liver, lung or pancreas;
- bone, tendons and ligaments to repair injuries;
- heart valves to replace defective heart valves; and
- corneas to restore eyesight.

Some examples of cell therapies currently being used, or currently under development, are:

- chondrocytes used for cartilage regeneration;
- isolated pancreatic islet cells for the treatment of diabetes; and
- mesenchymal progenitor cells for the treatment of musculoskeletal defects and in a range of other clinical applications such as cardiovascular repair.

What is the nature of the industry producing HCTs in Australia?

In the past, HCTs have primarily been "manufactured" by not-for-profit tissue banks (who have traditionally processed and stored tissues for future use) and by hospitals (who develop tissue therapies in house for use in particular patients). However, with recent advances in cell and tissue technology, there appears to be increasing involvement of the private sector in the manufacture of HCTs and the creation of small start-up companies and clinics within larger hospitals. During consultations, on the draft consultation RIS during the development of ANZTPA, it was also noted that medical devices manufacturers may, in the future, incorporate HCTs into the manufacture of medical devices.

As the TGA does not currently regulate all HCTs (refer discussion below), it is not possible to identify all organisations involved in the manufacture of HCTs. However, the TGA is aware of a number of companies (including small start-up companies) and organisations undertaking such work. These include, for example, Verigen (WA) and the Australian Stem Cell Centre Ltd (Vic).

The table at Attachment A has been based on information available as at December 2008 regarding the organisations within each jurisdiction that are believed to be undertaking work involving HCTs (or who are currently subject to TGA regulation). The information does not include any HCTs manufactured overseas that are currently regulated (as therapeutic devices) or may seek inclusion on the ARTG.

How are HCTs currently regulated by the TGA?

The *Therapeutic Goods Act 1989* (the TG Act) currently provides that all devices of human, animal, bacterial or recombinant origin for use in, or on, the body of a person, must be included on the Australian Register of Therapeutic Goods (ARTG). This means that they must have pre-market approval from the TGA and that the manufacturer of such devices must be licensed by the TGA.

However, there are a number of exemptions to this requirement:

- whole organs for transplant are excluded from regulation;

- human tissue for implantation in the human body that is obtained, stored and supplied without any deliberate alteration to its biological or mechanical properties is exempt from the requirements for entry on the Register provided that the Australian institution complies with the current Code of Good Manufacturing Practice – Human Blood and Tissues (cGMP for Human Blood and Tissues). This effectively means that banked tissue (such as heart valves, skin, corneas and bone) is exempt from inclusion on the Register provided that the Australian tissue bank complies with cGMP for Human Blood and Tissues;

- medicines (other than medicines for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person are exempt from the requirements for entry on the ARTG. Similarly those people that have traditionally developed such medicines are also exempt from the TGA's requirements for licensing of manufacturers – for example:

    - medical practitioners and health care workers are exempt from licensing requirements (and therefore compliance with the cGMP) provided that the "manufacture" of the HCT is for a patient under his or her care (and the medical practitioner himself/herself is developing the HCT); and
    - biomedical engineers, radiochemists and pharmacists in public hospitals are also exempt from licensing requirements provided that the goods produced are for supply in hospitals or public institutions in the same state or territory.

The TGA has, to date, interpreted the legislation to require that:

- tissue banks are licensed by the TGA and demonstrate compliance with cGMP for Human Blood and Tissues; and

- all people who are "manufacturing and supplying" human tissue or cellular therapies are required to be licensed as manufacturers and the HCT entered on the ARTG. There are, however, a number of exemptions or exceptions to this requirement:

    - if the tissue is an organ – excluded from the legislation;
    - if the tissue is reproductive tissue – excluded from the legislation;
    - if the HCT is custom made (or extemporaneously compounded) for a particular person – no requirement for entering on ARTG;
    - if the "manufacturer" is a medical practitioner, health care worker, pharmacist etc – no requirement to be licensed;

- if the HCT is for use in the treatment of a particular patient with special needs – patient must be notified to the TGA and supply for the particular case approved (Special Access Scheme - SAS) but no requirement for licensing or registration; and
- if the HCT is for use in a clinical trial – schemes relating to clinical trials apply (either CTX or CTN).

How are HCTs currently regulated by other countries?

United States –The US Food and Drug Administration (FDA) regulates human cells and tissues and cellular and tissue-based products (HCT/Ps) as biologics under 21 CFR Parts 1270 and 1271. Three Final Rules were published to broaden the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission and spread of communicable disease. The Rules require:

- cell and tissue facilities to register and list their HCT/Ps with the FDA;
- evaluation of donor eligibility through screening and testing to reduce the transmission of infectious disease through tissue transplantation; and
- Good Tissue Practice to be implemented.

The Final Rules apply to tissues recovered after 25 May 2005. The new regulatory approach was implemented in a staged process.

Highly manipulated cell and tissue products, for example somatic cell and gene therapy, are regulated more comprehensively, akin to a medicinal or Class III medical device product.

In the US, whole organ transplantation is regulated nationally through the *National Organ Transplant Act of 1984* and related Rules. The Act/Rules require, among other things, testing of donors, keeping of records (that must be available for inspection) and training of surgeons and physicians.

Europe – the European Commission and Parliament established a Directive for "setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells". The Directive includes requirements that all tissue establishments are accredited or licensed by a competent authority and that such tissue establishments have quality systems in place. A Directive (2006/17/EC) sets out the technical requirements for the implementation of Directive 2004/23/EC. The Commission proposal (COM(2005) 567 Final) notes that advanced therapies (such as gene and somatic cell therapies and tissue engineering) should be regulated as medicinal products to provide a '*robust and comprehensive regulatory framework*'.

The Official Journal of the European Union published Regulation (EC) No 1394/2007 of the European Parliament and of the Council (13 November 2007) on advanced therapy medicinal products, amending previous Directives, and putting into effect measures to be taken to ensure the safety, quality and efficacy of these often complex and innovative treatments.

Canada – Health Canada regulates HCTs via several routes depending on the nature/use of the product. For example:

- some cells and tissues, such as gene and somatic cell therapies are regulated as medicines;

- semen is regulated under the *Food and Drugs Act*;
- reproductive tissue is regulated under the *Assisted Reproduction Act*; and
- other HCTs are regulated as Class IV medical devices.

A revised Directive issued in 2005 provides basic requirements for safety of cells and tissues through prescribed National Standards. The Directive applies only to human organs and minimally manipulated cells and tissues intended for use as homologous allografts, and that are not Class IV medical devices, blood or blood derivatives or reproductive cells and tissues. Health Canada is developing a new regulatory framework under the *Food and Drugs Act* for cells, tissues and organs within the scope of the Directive, that will be informed by its National Safety Standards and include other key elements, for example, adverse event reporting and a compliance monitoring and enforcement strategy.

What is the current world supply of HCTs?

Overall world production and supply in HCTs is difficult to estimate. This is because either many regulatory agencies (except the FDA) have not released their records to the public or the regulation of HCTs is in the process of being implemented and comprehensive records do not yet exist.

Therefore, reliable information is not currently available about the number of companies that manufacture HCTs or the quantity of HCTs being supplied worldwide.

The limited information available from the US FDA records provides some indication of the increase in use of HCTs in recent years. The data indicates that:

- there were 1325 establishments registered for HCTs (as at 04 May 2004); increasing to 1974 registered establishments by 27 October 2005 and more than 2,000 by June 2007;
- for musculoskeletal tissues alone, the number of tissue transplants performed annually grew from 350,000 in 1990 to greater than 1,000,000 in 2004, and 1.5 million by 2007;
- the FDA conducted inspections on 111 tissue facilities in the period 1994-1997 (noting that some 36 tissue banks had never been inspected by the FDA). The number of inspections of HCT facilities per year doubled between 2001 (132) and 2005 (270), with a further increase evident with inspection of 408 major human tissue recovery facilities in the fiscal year 2007.

Given recent advances in technologies enabling the production of an increased range of HCTs, anecdotal information suggests that there has recently been an exponential increase in the HCTs becoming available for use. This is reinforced by the actions of a number of governments who have moved quickly to introduce specific regulation for this sector (rather than continuing to rely on regulation of general application to medicines and devices).

In particular, the March 2004 Directive of the European Parliament (on setting standards for quality and safety in relation to human tissues and cells), expressly notes in Article 5 that “As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards”. As agencies are proposing and publishing frameworks and technical requirements, international fora are being convened to draw comment and inform the implementation of the new requirements.

Problem

In Australia, the therapeutic goods framework is not currently well adapted to HCTs for a number of reasons.

- Lack of clarity. There is currently a complex web of provisions (including exemptions) relating to HCTs. Stakeholders have expressed concern that this lack of clarity may lead to unintentional non-compliance with regulatory obligations.

- Absence of a comprehensive risk based classification system for HCTs. Currently some HCTs are not regulated, some are regulated as medicines and some are regulated as therapeutic devices. Further, the level of regulation applied does not adequately reflect the risks posed by the various types of HCTs.

- Lack of international harmonisation. The TGA strongly supports harmonisation of regulatory requirements with other countries and is involved in a number of international fora directed towards achieving greater harmonisation in the regulation of therapeutic goods. Over the past few years, the U.S., U.K., Europe and Canada have all implemented (or are in the process of developing and implementing) new systems for the regulation of HCTs that are risk based, do not rely on the traditional model of regulation for medicines and devices and enable the regulatory authorities to respond to changes in technology. The TGA's current regulation of HCTs is not consistent with the revised approaches being adopted by these other countries.

- Problems regarding application of the cGMP for Medicinal Products to certain HCTs. Currently HCTs that are regulated as medicines must comply with the cGMP for Medicinal Products. However, the cGMP for Medicinal Products is not well adapted for dealing with the unique circumstances surrounding HCTs (including for example, the lack of control over starting materials and the fact that many HCTs are not batch produced but produced for a particular patient using that patient's cells).

Objectives

The objectives of Government action are:

- to increase regulatory certainty for the use of HCTs as therapeutic goods;
- to ensure a risk based approach to regulation and to ensure that the level of regulation applied is commensurate with the level of risk posed by the particular product;
- to ensure that there is flexibility in any new regulatory framework in order to respond to changes in technology;
- to increase the degree of international harmonisation; and
- to ensure that any regulatory requirements, including any possible future harmonisation with other countries, are appropriately adapted to the unique conditions surrounding the supply of HCTs and do not impose an unnecessary burden on industry.

Options and Impact analysis

Groups likely to experience the benefits and costs

The groups likely to be affected by changes to the regulation of HCTs are manufacturers of HCTs, Tissue Banks, consumers and Governments.

Manufacturers of HCTs (other than tissue banks)

Manufacturers of HCTs may potentially include a wide range of people including medical practitioners within hospitals (who develop HCTs on site), commercial organisations specialising in the manufacture of HCTs, medical devices manufacturers who incorporate HCTs into medical devices, laboratories developing HCTs and tissue banks (refer below). As at November 2008, there were approximately 7 organisations responsible for overseeing organ transplantation (who are currently not regulated by the TGA), 61 ART clinics (24 primary with 37 satellite clinics) responsible for banking reproductive tissue (also not currently regulated by the TGA) and 11 facilities (excluding tissue banks) licensed by the TGA to manufacture cellular therapies – 6 of which are cGMP compliant and 5 whose products are both cGMP compliant and included on the ARTG[1].

Tissue Banks

As at November 2008, there were approximately 19 licensed tissue banks operating in Australia including bone banks, eye banks, heart valve banks and skin banks.

Consumers

The regulation of HCTs directly impacts on consumers of such therapies who have an expectation that the therapies are safe, efficacious and of high quality. As the TGA is a fully cost-recovered agency, any costs of regulation may also be indirectly borne by consumers (through increased costs of HCTs).

Governments

Commonwealth, state and territory governments are all likely to be affected by any changes to the regulation of HCTs. This is not only because all play a role in the national regulatory framework for therapeutic goods, but also because any changes to the regulation of HCTs within, for example, hospital settings, may have cost implications for state/territory governments that fund such hospitals.

Options

Three options have been considered for the regulation of HCTs.

[1] Please note that the total number of licensed HCT manufacturers is not static and changes as more manufacturers are licensed and others notify the TGA that they are no longer manufacturing.

Option 1: Retain the Status quo. This would mean that:

- if the tissue is an organ or reproductive tissue it would be excluded from any regulation;

- banked tissue (such as heart valves, skin, corneas and bone) would be exempt from inclusion on the ARTG provided that the Australian tissue bank is compliant with cGMP (i.e. has a manufacturing licence);

- a HCT whose principle therapeutic purposes are achieved through chemical, pharmacological, or metabolic actions would be regulated as a medicine. HCTs of this kind would be required to be entered on the ARTG and the manufacturer of the HCT would be required to be licensed and comply with the cGMP for Medicinal Products;

- a HCT that is not a medicine and is produced by deliberate alteration of tissues or cells in defined manufacturing processes would be regulated as a "therapeutic device";

- a HCT that is produced or prepared for a particular person (autologous use) would:

    - be exempt from the ARTG requirements if the HCT is defined as a medicine (that is, an HCT whose principle therapeutic purpose is achieved through chemical, pharmacological or metabolic actions);

    - be exempt from the requirements for the "manufacturer" to be licensed and comply with the cGMP for Medicinal Products if the HCT is defined as a medicine (as described above) and the manufacturer is the medical practitioner who is himself/herself manufacturing the HCT for a patient under his or her care; or

    - be required to be entered on the ARTG (and the manufacturer licensed as compliant with cGMP for Human Blood and Tissues) if the HCT is a human derived HCT that is not a medicine and is produced by deliberate alteration of tissues or cells in defined manufacturing processes.

Option 2: Regulate **all HCTs** as medicines or therapeutic devices and remove the exemptions for whole organs, reproductive tissue (ART) and HCTs produced or prepared for a particular person or by a medical practitioner for their own patient (except if the HCT forms part of a single surgical procedure).

This would mean that all manufacturers of HCTs would be required to comply with the cGMP for Medicinal Products or the Australian Code of Good Manufacturing Practice – Human Blood and Tissues (cGMP Human Blood and Tissues) applicable to human origin therapeutic devices, and all HCTs would be required to be evaluated by the TGA and entered on the ARTG.

Option 3:
The previous RIS approved during the development of the Biologicals framework under ANZTPA outlined option 3 as below. Since moving forward with consideration of the framework in an Australia-only context, minor amendments have been made to reflect decisions taken by Government. These are detailed at end of the option.

Regulate HCTs as a discrete class of therapeutic goods within a new "Biologicals" framework as follows:

- there would be four classes of HCTs with varying levels of regulation applying, based on the risk of the HCT;

- the four classes would be as follows:

  - Class 1 - Organs that are for direct transfer from donor to recipient (other than part of a single surgical procedure) and reproductive tissue (other than reproductive tissue that has been manipulated such that it would fall in a higher class).

  - Class 2 - A tissue or cell that is stored, maintained or preserved for future use and: is not a Class 3 or 4 HCT; is not for direct transfer from donor to recipient; and is not reproductive tissue.

  - Class 3 - A cell or tissue processed in a manner that may alter the structure and properties of the cell or tissue but does not purposefully alter the biological activity.

  - Class 4 - A cell or tissue that is processed so that the biological properties are deliberately manipulated or used for a purpose that is not the usual biological function of the cell or tissue.

- the level of regulation applied to each class would be as follows:

  - Class 1 - Applicants would attest to compliance with relevant Standards (based on industry standards), through the submission to the TGA of a Declaration supporting TGA issuance of a Class 1 HCT Licence.

  - Class 2 - Applicants would be required to demonstrate compliance with Manufacturing Principles (which will replace the existing cGMP for Human Blood and Tissues) and compliance with relevant Standards for each tissue type (resulting in the issuing of a Class 2 HCT licence).

  - Class 3 - Applicants will be required to demonstrate compliance with Manufacturing Principles and demonstrate that the particular HCT is safe, efficacious and of high quality through the submission of a Dossier (resulting in the issuing of a Class 3 HCT licence).

  - Class 4 – As for Class 3 except that the Dossier would also need to contain relevant clinical data and analysis.

- Exemptions would apply to:

  - single surgical procedures performed on one patient (autologous transplant) and single surgical procedures involving two patients (non-autologous or allotransplant) such as organ donation from a live donor within the same facility as the transplant recipient; and

- exceptional release/acceptance. The TGA would set standards that must be complied with by organisations. Exceptional release/acceptance of an organ or cells is a mechanism by which organisations can release/accept organs/cells when there are justified non compliant organs and cells (for example, an organ or cells infected with HCV).

As noted, the above option was developed during the establishment of the now postponed ANZTPA and is now to be taken forward in an Australia-only context. In light of this, minor modifications are to be made to the option.

The Australian Government has identified that a new organ donation and transplantation authority is to be established and, therefore, regulation of organs is no longer required under the new Biologicals framework. Similarly, a decision has been taken by the Government that, at this time, un-manipulated reproductive tissues should not be subject to additional regulation as the ART sector has been assessed as being managed coherently and consistently.

Therefore, organs and ART would be excluded from the framework, at least initially, as identified in the "Report to the Australian Parliament As Prescribed under Section 47C of the *Research Involving Human Embryos Act 2002*"

As the framework would now be developed within the existing Australian TG Act, the licensing arrangements would no longer apply and approved HCTs would instead be included on the ARTG in the relevant class to which they were approved.

Slight modification to the classes of HCTs has also been proposed under this option in an Australian-only context, in part reflecting also the exclusion of organs and ART. The revised classifications therefore, would be:

- Class 1 - HCTs that are:
  - Not banked (that is, stored for future use);
  - Not processed (that is, manufactured by a process other than minimal primary separation); and
  - Is not a Class 2, 3 or 4.

- Class 2 – HCTs that are:
  - Stored, maintained or preserved for future use (ie: not for direct transfer from donor to recipient); and
  - is not a Class 1, 3 or 4 HCT.

- Class 3 - HCTs that are:
  - Processed in a manner that may alter the structure and properties of the cell or tissue but does not purposefully alter the biological activity; and
  - is not a Class 1, 2 or 4.

- Class 4 - HCTs that are:
  - A cell or tissue that is processed so that the biological properties are deliberately manipulated; or

- Processed for a purpose that is not the usual biological function of the cell or tissue; and
- is not a Class 1, 2 or 3.

The level of regulation applied to each of the above would be the same as previously detailed, noting that successful applications would result in inclusion on the ARTG rather than a licence.

The exemption category for single surgical procedures would remain the same and noting the framework would not apply to organ donation / transplant. The exceptional release/acceptance exemption would be modified slightly to reflect that it would provide for 'tissues or cells' rather than 'organs or cells' to reflect the decision not to include organs in the framework.

Impact analysis

The following impact analysis has been revised to reflect additional information and Government decisions since the original decision in 2006. This also reflects the decision to take forward regulation of HCTs in an Australia-only context following the postponement of ANZTPA. The revised financial impact figures do not, however, alter the ranking of the options by net benefit from the RIS agreed in 2006.

The following impact analysis describes the likely impacts (benefits and costs) to all stakeholders, including the likely compliance costs to industry. In developing this analysis, the OBPR "Business Cost Calculator" (BCC) has been utilised.

In assessing the costs to business, the individual business costs associated with preparing applications, purchasing necessary equipment etc has not been assessed as these will vary greatly between businesses including depending on their existing level of compatibility with the options. As such, the BCC and this impact analysis assesses the broad impacts and relative compliance costs (in general terms) in relation to the three options. The TGA has consulted extensively with interested parties regarding the options outlined within this RIS and specifically in regard to the details of the preferred option 3 to develop the necessary legislative changes and underpinning documentation which will set out the detail of the scheme.

Impacts of Option 1: Retain the status quo

Manufacturers of HCTs: Confusion would continue to exist and the regulation of HCTs would not depend on the risk posed by the HCT but the nature of the manipulation, "who" is manufacturing the HCT and whether the HCT is defined as a medicine or an "other therapeutic good". Some manufacturers of HCTs would be subject to regulation and others would not.

There would continue to be uncertainty regarding the application of the legislation and the exemptions. A continued absence of international harmonisation may also lead to increased costs for sponsors/manufacturers supplying HCTs to Australia and other countries.
In relation to compliance costs, there would be no change because the status quo would be maintained. Some manufacturers would continue to be required to pay regulatory fees where the HCT is deemed a medicine or device while others, not covered under these categories,

would remain either unregulated and consequently not be required to pay such fees or required to only comply with cGMP.

Tissue Banks: This option would have minimal impact on tissue banks (provided that such tissue banks do not manipulate tissue but simply obtain, store and supply tissue without any deliberate alteration to the mechanical properties of the tissue). Tissue banks would continue to have to be licensed by the TGA as manufacturers and comply with the cGMP for Blood and Tissues. If a tissue bank was to manipulate or modify the HCT then they would face similar difficulties to other manufacturers of HCTs (as discussed above).
In relation to compliance costs, there would be no change because the status quo would be maintained.

Consumers: As organs and reproductive tissue would continue to be exempt from regulation it could be argued that consumers would not be assured that the use, quality and safety of HCTs is subject to consistent, national oversight.
Because organs and reproductive tissue are not currently regulated by the TGA, the TGA is not formally advised of any adverse incidents relating to organs or reproductive tissue. However, in the USA there have been reports of transmission of infectious diseases such as HCV, West Nile Virus and Rabies which have heightened awareness and concern about these issues in Australia. These concerns have caused some consumers and governments to support the need for greater government intervention in the oversight of these therapies. Transmission of diseases is also a key concern for HCTs more broadly and it is recognised that current arrangements do not consistently or adequately regulate to ensure the safety of these therapeutic goods. This option would, therefore, not address this concern and provide the level of quality assurance expected by consumers.

Government: This option would not impose any increased costs on government. Governments could, however, be criticised for their failure to effectively oversee this area of therapeutics particularly in the event of a severe adverse event in Australia.

Impacts of Option 2: Regulate all HCTs as medicines or devices under the existing framework for these and remove the exemptions for whole organs, reproductive tissue (ART) and HCTs produced or prepared for a particular person (except if the HCT forms part of a single surgical procedure).

Manufacturers of HCTs: As is currently the case, difficulties would be encountered through the regulation of HCTs as medicines or devices. This is because HCTs are not manufactured in the same manner as most medicines and the therapeutic properties are often quite different.

For example, HCTs are generally not produced in batches, can not readily be defined by the dosage form, strength or pack size or indications and those developing and applying HCTs have limited control over the starting material because it is human derived. Terminal sterilisation/filtration and pathogen elimination can also be more difficult.

Applying the requirements relating to medicinal products to HCTs would lead to significant increased costs to manufacturers of HCTs where they are not currently regulated as medicines or devices. Similar issues would also arise in relation to the regulation of HCTs as devices and uncertainty would continue to exist regarding which HCTs fall within the definition of “medicines” and which fall within the definition of “medical devices”. Organs,

for example, have been considered as medicines in the BCC due to their metabolic action, although they may also be considered as devices. Small companies introducing HCTs to the market for the first time may face particular challenges complying with the current cGMP for Medicinal Products.

The removal of the current exemptions for whole organs would mean that there is national oversight of all uses of HCTs (including organs). However, requiring those involved in organ transplants and banked reproductive tissue to apply the cGMP for Medicinal Products would be unworkable and impose enormous costs on those involved. The major problem with this option is that the level of regulation applied would be the same regardless of the risk posed by the HCT. This would lead to significant over-regulation for most HCTs (including organs and ART) and resulting increased costs to manufacturers.

In terms of overall compliance costs, there would be significant compliance costs for organ donor co-ordinating agencies and IVF units as the result of the need to comply with cGMP. While many IVF clinics already voluntarily comply with cGMP, this is not the case in relation to organs.

For products that are already regulated as medicines or devices there would be no change from Option 1 (no increase in compliance costs) and for new products the compliance cost are likely to be similar for this option as for Options 1 and 3.

Tissue Banks: If tissues stored in tissue banks were regulated as medicines (or therapeutic devices) and the cGMP for Medicinal Products (or the essential principles for medical devices) was applied rather than the cGMP for Blood and Tissues this would have a significant negative impact and cost impost on tissue banks. If this were the case, the overall compliance costs for tissue banks would be greater for this option than for any other option.

Consumers: This option provides a high level of assurance to consumers that all HCTs are thoroughly regulated. However, if manufacturers were to pass on the increased costs to consumers, increased costs would also be likely to borne by consumers.

It could also be argued that if the costs of compliance were too high (as they would likely be if all manufacturers of HCTs were required to comply with the cGMP for Medicinal Products or the essential principles and conformity assessment procedures for devices), low volume HCTs may be withdrawn from the market. This could potentially reduce treatment options for patients. Further, imposing the medicinal product regulation framework on whole organs may also create delays for transplantation where organs are subject to cGMP requirements.

Government: This option would have a significant impact on both state and territory governments and on the Commonwealth government. The removal of the current exemptions would expand the class of manufacturers that are required to comply with the cGMP for Medicinal Products (or medical devices conformity assessment procedures). This would include publicly funded hospitals that may need infrastructure changes in order to meet the requirements relating to medicines and therapeutic devices. Further, as the TGA is a fully cost recovered agency there would also be regulatory fees and charges that, in the case of publicly funded institutions, would ultimately be passed onto state and territory governments.

Impacts of Option 3: Regulate HCTs as a separate type of therapeutic good, Biologics, with four classes of HCT each with a different level of regulation based on the level of risk posed

The following impact overview for this option has been revised minimally to reflect the further government decisions since 2006, as noted above. These are essentially reflected in the four proposed classes for HCTs.

Manufacturers of HCTs: This system would provide greater certainty to manufacturers (resulting in less confusion regarding the TGA's regulatory requirements) and would be consistent with the approach adopted by the U.S., Canada, and Europe. This would minimise costs to organisations that are supplying HCTs to multiple countries.

Manufacturers who are currently subject to existing regulatory requirements will have to adapt to complying with the new regulatory regime and this may impose some costs on such manufacturers.

Under this option, organs and reproductive tissues would continue to be regulated under the arrangements they are currently, and not as HCTs, due to the issues identified at Option 2 above for these biologicals.

For HCTs that are not banked, stored or processed (Class 1), there will be a new requirement for an application to be made to the TGA attesting compliance with basic Standards. As the TGA Standards will be based on existing industry Standards, it is not expected that there will be a significant increase in compliance costs for those involved in the supply of class 1 HCTs as there should be no additional infrastructure costs compared with Option 1 (status quo). A small compliance cost would result from completing paper work for submission to the TGA.

In terms of compliance costs for manufacturers of Class 2, 3 and 4 biologicals, this will vary depending upon the requirements for that class which will be based on a risk approach and whether it is currently subject to regulation. For example, for products that are currently regulated by the TGA as a medicine or device, there is unlikely to be any increase in compliance costs compared with Option 1.

For organisations seeking approval of new biologicals, the compliance costs will depend on the class of the biological. However, the cost of complying with Option 3 would be no greater than the cost that would be incurred by an organisation that needed to meet the existing regulatory requirements for medicines or medical devices (Option 1) or the requirements under Option 2.

For manufacturers who are manufacturing Class 3 or Class 4 HCTs that are currently exempt from TGA regulation (such as medical practitioners manufacturing HCTs for a particular patient) there will be an increase in compliance costs compared with Option 1 (but costs will not be as great as they might be under Option 2). The magnitude of these costs will depend on the "starting point" of the organisation regarding if the biological is currently regulated as a medicine or device. The inclusion of an exemption for HCTs that are removed and reimplanted in a single surgical procedure would ensure that routine medical practice is not inappropriately captured by the TGA regulatory system.

Tissue Banks as a major industry group for HCTs: This option would have minimal impact on tissue banks because they are already required to comply with cGMP for Human Blood and Tissues. Under this Option it is intended that tissue banks will be required to comply with new Manufacturing Principles – these are intended to be better adapted to HCTs, less prescriptive and more outcomes focused. This change is therefore not expected to increase compliance costs.

In addition to the change to the Manufacturing Principles, under this Option tissue banks will also be required to comply with relevant Standards and to submit a Standards file or dossier to the TGA for class 2, 3 or 4 HCTs. This is unlikely to be a major impost as the file or dossier would draw heavily on the information that tissue banks are already required to hold as part of their cGMP compliance. Further, if the HCT is of class 3 or 4 it would already be regulated as a therapeutic device under current regulatory requirements, therefore, the arrangements under Option 3 would be no more onerous.

It is, therefore, not expected that there will be any significant additional compliance costs for these manufacturers. It is expected that there will, however, be some compliance costs as a result of preparing a Standards File or dossier for submission to the TGA as part of the approval process. These small cost are likely to be greater than the costs associated with Option 1 (where there is no requirement for submission of a Standards file) but lower than the costs associated with Option 2 (where a full safety, quality and efficacy assessment would be undertaken).

Class 1 HCTs would not be required to submit standards files or dossiers as there is a lower level of regulatory requirements commensurate with their risk profile. Therefore, the regulatory costs for these HCTs would be less than under option 2 but possibly more than under option 1 if they are not already required to comply with medicine or device regulatory requirements.

Consumers: This option provides a high level of assurance to consumers that all HCTs are regulated appropriately based on risk and that manufacturers of HCTs are subject to the same standards regardless of who they are. Where there are increased costs to industry as a result of complying with the new requirements these may be passed on to consumers (although such costs would be significantly less than the costs associated with Option 2).

It is possible that certain Class 3 or Class 4 HCTs that are currently produced by a medical practitioner for a particular individual will not be available because the medical practitioner would not be able to meet the required Manufacturing Principles. However, this risk is low and the more probable eventuality will be consolidation of activities and expertise within a more limited number of centres rather than in a number of very small operations in multiple hospitals/university laboratories. Further, the schemes for the supply of unapproved products (currently the clinical trials schemes and the special access schemes) would continue to operate.

It could also be argued that if an HCT falls within Class 3 or Class 4 (higher risk) and is not being manufactured to appropriate safety and quality standards then such HCTs should not be supplied to patients and the additional regulation ensures that such HCTs are not so supplied.

Government: As detailed above, some manufacturers of Class 3 of Class 4 HCTs that were previously exempt would be regulated by the TGA under this Option.

Where Class 3 or Class 4 HCTs are being manufactured in a State/Territory funded hospital (and are not currently required to be manufactured in accordance with either the cGMP for Medicinal Products or the cGMP for Human Blood and Tissues) then there are likely to be additional costs to State/Territory governments as a result of possible improvements needed to the physical environment in order to meet the new Manufacturing Principles. As the TGA is a fully cost-recovered agency, there will also be costs associated with the TGA's regulation of HCTs that may in some cases be borne by State governments through funding of public hospitals.

Consultation

What consultation has been undertaken to date?

Consultations on the regulation of biologicals were undertaken during the development of ANZTPA. Following the postponement of the joint agency in July 2007, further consultations were undertaken in the context of an Australia-only regulatory framework. The following outlines both phases of consultation.

Post-ANZTPA consultations

In late July and early August 2008 the TGA completed stakeholder consultations on a number of regulatory reforms proposed for each therapeutic product sector including biologicals. The consultations were not intended to re-open discussion on issues already considered and agreed as part of the reforms to be adopted when establishing the joint regulatory scheme but to provide an opportunity for discussion of how these reforms were to be implemented in the Australian context.

In regard to biologicals participants were advised that the regulatory proposal is that agreed by AHMC and AHMAC in 2006: a risk-based approach dependent on the extent of manipulation applied to the tissues or cells and whether the end-use is homologous. Inclusion on the ARTG and requirements for quality managements systems would apply to medium and high risk products.

Participants noted that changes to both the Act and Regulations are required and that the proposed legislative changes were expected to be introduced in the autumn 2009 sitting of the Australian Parliament.

It was noted that assisted reproductive technologies and solid organs are subject to further discussions and will be excluded from consideration within the biologicals framework at this time.

Initial consultations during the development of ANZTPA (2002 and 2003)

- Initial consultations with key stakeholders to inform the preparation of a Discussion Paper on the Regulation of Human Tissues and Emerging Biological Therapies.

- Publishing of a Discussion Paper (sent to over 135 stakeholders and posted on the TGA website).

- Workshops were held in each capital city, with the exception of Darwin (cancelled due to a lack of response) - over 135 attendees. Written submissions received from 27 individuals and organisations.

- A Facility Registration Survey circulated to all organisations involved in the manufacture of HCTs (for voluntary completion). The purpose of this was to enable the TGA to more accurately assess the number (and nature) of organisations likely to be affected by the proposed scheme for HCTs.

Expert Advisory Group

- Formation of an Expert Advisory Group, chaired by the Commonwealth's Chief Medical Officer, in early 2004 to advise on issues relating to the development of an appropriate regulatory framework for biological therapies including HCTs.

Further stakeholder consultations (2004 - 2006)

- Further consultations with peak bodies and experts including the IVF industry, Eye Banks of Australia and New Zealand, the Transplantation Society of Australia and New Zealand, Australians Donate and the Australasian Tissue Banking Forum.

- A further round of public fora in 2004 (over 250 stakeholders attended Australia wide). Two fora were held in Sydney and one forum was held in each of the other capital cities excluding Hobart and Darwin.

- A joint symposium between TGA and NATA in June 2004 in response to stakeholder concerns about the possible overlap between the roles of NATA and the TGA in the regulation of HCTs.

- Publication of a consultation draft of this RIS (posted on the TGA website and emailed to 250 stakeholders). Approximately 20 written submissions received.

- Consultation with all jurisdictions including through a number of workshops held throughout the latter part of 2005 and 2006.

What are the views of the affected parties?

As would be expected, as the consultations progressed the issues raised by stakeholders became more specific. During the early consultations, the main issues that arose were as follows.

- The proposed scope of Option 3 and what should be "in and out" of the proposed new regulatory scheme for HCTs. For example, the question of whether whole organs and reproductive tissue should be included in the regulatory scheme was discussed. Some industry stakeholders agreed that whole organs and reproductive tissue should be included in the regulatory scheme for HCTs but they noted that it is important that the level of regulation applied is appropriate and that the unique circumstances surrounding organ transplantation and reproductive tissue are acknowledged (including the difficulties

inherent in applying any GMP-like requirements to whole organ transplants). Others, particularly some jurisdictions, suggested that the regulation of organs should be deferred.

- The appropriate risk classification of HCTs. Overall it was acknowledged that dividing the system into classes based on risk was an appropriate means for applying regulation. The main issues raised by stakeholders in relation to the risk classification of HCTs were ensuring that all relevant factors were taken into account in determining the risk classification of HCTs and the importance of the classes, in combination, capturing all tissues and cells, so that certain HCTs do not "fall through the gaps".

- The level of regulation proposed to be applied to each Class of HCT. It was generally agreed that:

  - organs should not be subject to GMP requirements;

  - it is appropriate for tissue banks to continue to essentially be regulated as they currently are.

  - Class 3 and Class 4 HCTs should be subject to full evaluation by the TGA for safety, quality and efficacy.

- The desirability of international harmonisation. It was recognised that the proposed approach is consistent with the US approach whereby all HCTs must meet certain minimum standards but only certain defined HCTs are considered higher risk and therefore necessitating greater regulatory oversight.

- The appropriate exemptions. Stakeholders generally agreed that cells or tissues that are removed and reimplanted as part of a single surgical procedure should be exempt from regulatory oversight by the TGA. This has been reflected in proposed Option 3.

During later consultations, specific issues raised included:

- the minimum standards to be applied to Class 1 HCTs. Industry stakeholders strongly supported basing the national minimum standards on existing industry standards;

- the Manufacturing Principles to be applied in respect of Class 2 and Class 3 (including Class 4) HCTs. Stakeholders strongly emphasised the importance of developing the new Manufacturing Principles in close consultation with all stakeholders and noted that the Manufacturing Principles should be less prescriptive than the current Code of GMP for Human Blood and Tissues. It was considered that the Manufacturing Principles should focus on the principles or standards to be observed rather than detailing prescriptive means for meeting such standards.

- The costs of compliance and the TGA's policy of cost recovery. Two main issues were raised during consultations. Firstly it was noted that fees charged by the TGA are not the only costs that will be borne by organisations who are subject to any new regulation and that there would be costs for some organisations associated with upgrading infrastructure in order to comply with new requirements. The majority of stakeholders considered that Commonwealth, State and Territory governments should provide the necessary funds for

public and not-for-profit organisations to comply with the regulatory system and meet the costs imposed by the TGA.

On the whole it appeared that stakeholders supported Option 3 and it was generally agreed that the current situation is unsustainable and can lead to unintentional non-compliance because of the complexities of the exemptions and regulations.

Conclusion and recommended option

The major disadvantage of Option 1 (status quo) is that it does not address the problems identified in this RIS (and is not consistent with the agreement of AHMC that the TGA introduce a new regulatory scheme for HCTs). This would mean that the problems associated with lack of regulatory certainty, lack of flexibility to respond to changes in technology, the absence of a comprehensive risk based system for the regulation of HCTs and the absence of international harmonisation would continue to exist.

During consultation on the draft RIS during the development of ANZTPA, stakeholders reinforced concerns regarding unintentional non-compliance and the lack of a risk based system that does not acknowledge the level of manipulation applied or the rapid development of technology in this area.

There would also continue to be differences in the level of regulation applied depending on "who" manufactures the HCT and whether the nature of the manipulation of the HCT means that the HCT is defined as a medicine or a therapeutic device.

The advantage of Option 2 is that it addresses some of the problems identified in relation to Option 1 by removing the exemptions for certain classes of manufacturers and ensuring that organs and banked reproductive tissue are subject to oversight. However, it creates significant additional problems by applying the medicines (or therapeutic devices) framework to the regulation of all HCTs including organs and reproductive tissue. These frameworks are not well adapted to HCTs and there would be significant increased costs (and disruption) if the cGMP for Medicinal Products was applied to all HCTs (or if the conformity assessment procedures for medical devices were applied). Option 2 was not supported by stakeholders.

The advantage of Option 3 is that it ensures that:

- HCTs would be regulated according to the risk posed;

- there would be clarity regarding the regulatory requirements (reducing confusion and inadvertent non-compliance);

- compliance costs are kept to a minimum. Compliance costs would be less under this Option than under Option 2. Compared with Option 1, there would only be a small increase in compliance cost, largely associated with the shift to the new framework;

- minimum national standards would apply to all HCTs providing a greater level of assurance to consumers that the risks associated with the manufacture and supply of HCTs are being managed; and

- the Australian regulatory requirements would be broadly consistent with the requirements of the US, Canada and the EU.

It is therefore recommended that Option 3 be adopted. This Option was supported by the majority of stakeholders who made submissions on the draft RIS during development of ANZTPA. Since that time a decision has been taken to not apply the HCT regulatory framework of option 3 to ART and whole organs as noted under option 3 above. This is consistent with the views expressed by some stakeholders during consultations including recent consultations in July/August 2008.

Implementation and Review

Should the recommendation included in this RIS be accepted, it is proposed that the new regulatory framework for HCTs would be set out in a new part in the TG Act. The Standards for HCTs and the Manufacturing Principles would also reflect consultations undertaken with stakeholders.

It is proposed that the new framework will be incorporated into the TG Act in 2009 with regulatory implementation occurring over a three year period to enable both the TGA and industry to transition across to the new arrangements.

Attachment A – HCT Facilities in Australia

State	Tissue / Cell Type	Number of HCTs identified	Estimated number anticipated for inclusion on ARTG under option 3
ACT	IVF	2	0
	Organs	1	0
	Tissue banks	1	1
	Cellular and Tissue therapies	0	0
NSW	IVF	24	0
	Organs	1	0
	Tissue banks	5	5
	Cellular and Tissue therapies (clinical trial)	1	1
NT	IVF	1	0
	Organs	1	0
	Tissue banks	0	0
	Cellular and Tissue therapies	0	0
QLD	IVF	16	0
	Organs	1	0
	Tissue banks	3	3
	Cellular and Tissue therapies	1	1
SA	IVF	2	0
	Organs	1	0
	Tissue banks	2	2
	Cellular and Tissue therapies	1	1
TAS	IVF	2	0
	Organs	0	0
	Tissue banks	1	1
VIC	IVF	10	0
	Organs / Donation coordination	1	0
	Tissue banks	5	5
	Cellular and Tissue therapies	4	4
WA	IVF	4	0
	Organs / Donation coordination	1	0
	Tissue banks	3	3
	Cellular and Tissue therapies	1	1

Note – the above table does not reflect HCTs, manufactured overseas, that are already on the ARTG as devices or that may seek inclusion on the ARTG under the options presented in this RIS.

THERAPEUTIC GOODS AMENDMENT (2009 MEASURES NO. 3) BILL 2009

NOTES ON CLAUSES

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Bill, once enacted, as the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2009*.

Clause 2: Commencement

This clause provides that the Bill commences on Royal Assent and that the various Schedules commence as set out in the table.

Schedule 1 will commence on a day to be proclaimed within 12 months of Royal Assent of the Act. This timeframe will provide time for subordinate legislation, provided for under the Schedule, to be drafted and also to allow time for industry to make any arrangements to enable compliance with the new arrangements.

Schedules 2 to 6 will commence the day after Royal Assent. This is because it is important that the Government is able to ensure those acting for the Commonwealth under the Act are not subject to specified civil proceedings, enable recall of specific batches of therapeutic goods, seek information from past sponsors and manufacturers, collect unpaid charges and implement other minor amendments immediately following Royal Assent.

Clause 3: Schedules

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the relevant Schedule, and any other item in a Schedule to this Bill has effect in the way set out in the provision. The Bill makes amendments to the *Therapeutic Goods Act 1989* (the Act) and includes application and transitional provisions.

SCHEDULE 1 – Biologicals

This Schedule superposes a new Part 3-2A on Part 3-2, in Chapter 3 of the Act. This new Part includes provisions to implement a new framework for the regulation of biological therapeutic goods (Biologicals).

The framework was initially developed to be implemented in a trans-Tasman context under the joint Australia New Zealand Therapeutic Products Authority (ANZTPA). Following the postponement in 2007 of ANZTPA the framework is now being implemented in an Australian-only context through amendments to the Act under this Schedule.

The enforcement measures and sanctions applying to biologicals as set out in this Schedule reflect the enforcement measures and sanctions in place currently under the Act applying to other therapeutic goods. The applicable sanctions (for example, offences and civil penalty provisions) and high levels of penalty reflect the risks to public health where unapproved biologicals are supplied or where requirements are not met to ensure their safe and effective use.

Item 1
This item inserts a new definition of ***biological*** at subsection 3(1). This item sets out that a biological has the meaning given by new section 32A (item 25 refers).

Item 2
This item inserts a new definition of ***biological number*** in relation to a biological at subsection 3(1). This provides for a unique identifier number to be attributed to a biological in relation to its inclusion in the Register.

A biological number means either the number that is assigned to the biological under subsection 32DB(2), 32DF(2) or 32DN(5), or if a different number is assigned to the biological, in accordance with regulations made for the purposes of paragraph 9A(4)(ca) (item 14 refers), then that number is the biological number.

Item 3
This item inserts a new definition of ***Class 1 biological*** and provides that such biologicals are as prescribed by the regulations made for the purposes of section 32AA and are a class referred to in those regulations as Class 1 biologicals (item 25 refers).

Item 4
This item repeals and replaces the definition of ***included in the Register*** at subsection 3(1) to reflect the inclusion in the Register of biologicals under new Part 3-2A (item 25 refers) in addition to medical devices included under Chapter 4.

Items 5 and 6
These items amend the definitions of ***medicine*** and ***therapeutic device*** at subsection 3(1) to make it clear that biologicals are therapeutic goods that are distinct from medicines and therapeutic devices, or that biologicals are not medicines or therapeutic devices.

Item 7
This item amends the definition of ***therapeutic goods*** at subsection 3(1) to reflect that therapeutic goods include biologicals.

Item 8
This item amends section 6AAE of the Act. Subsection 6AAE(1) of the Act provides that where a corresponding State law confers on a Commonwealth officer or Commonwealth authority the function of including goods in the Register or the power to include goods in the Register, the officer or authority may include the goods in the Register in accordance with the corresponding State law.

Subsection 6AAE(6) provides that a reference to the inclusion of the goods in the Register is a reference to the inclusion of the goods in the relevant parts of the Register. This item amends subsection 6AAE(6) by inserting a new paragraph referring to the part of the Register for biologicals included under new Part 3-2A (item 25 refers).

Item 9
This item amends paragraph 7B(1)(b) to provide that a package and therapeutic goods together constitute a kit for the purposes of the Act if each item of the therapeutic goods consists of particular therapeutic goods, and the package and therapeutic goods do not constitute a composite pack or a system or procedure pack.

Item 9 amends paragraph 7B(1)(b) to the effect that a package that contains a biological that is either included in the Register under Part 3-2A or is exempted under 32CA or 32CB under that new Part (item 25 refers), will be considered a kit for the purposes of the Act if the package and the biologicals are for use as a unit and do not constitute a composite pack or procedure pack.

This amendment provides, therefore, that a kit may contain both a biological and a medicine (but does not require that it does).

Item 10
This item amends subsection 9(1) of the Act to extend its application to evaluation of biologicals by the states, the Australian Capital Territory or the Northern Territory, on behalf of the Commonwealth, for inclusion in the Register under Part 3-2A, other than Class 1 biologicals (as they require assessment rather than full evaluation).

Items 11 to 14
These items amend section 9A of the Act in relation to including therapeutic goods in the Register to reflect the inclusion of biologicals in the Register.

Items 11 and 12 amend subsection 9A(3) to provide that the Register is to be expanded from three parts to four to accommodate a new part being for biologicals included under Part 3-2A of the Act. Item 12 makes it clear that the Register is now to contain a part for biologicals included under new Part 3-2A of the Act.

Item 13 repeals and replaces paragraph 9A(4)(b) to enable regulations made under subsection 9A(4) to prescribe the ways in which goods that are included in one part of the Register may be transferred to another part of the Register.

Subsection 9A(4) currently only allows the transfer of registered goods to the part of the Register for listed goods and the transfer of listed goods to the part of the Register for registered goods. This amendment expands and simplifies this paragraph to remove references to the transfer of therapeutic goods between specified parts of the Register, to transfer between any part of the Register. This means, for example, that a good registered under Part 3-2 of the Act can, in certain circumstances, be transferred to the part of the Register for listed goods, the part of the Register for biologicals included under Part 3-2A of the Act, or the part of the Register for medical devices.

Item 14 inserts new paragraph 9A(4)(ca) to enable regulations to be made that would allow a different biological number to be assigned to a biological that has already been previously assigned a biological number in relation to its inclusion in the Register under that part of the Register for biologicals.

Item 15
This item inserts new subsections 9D(3A) and (3B) about the variation of entries in the Register that relates to biologicals.

New subsection 9D(3A) empowers the Secretary to vary an entry in the Register in relation to a biological where an application is made by the person in relation to whom the biological is included, and where the Secretary is satisfied that the requested variation does not indicate a reduction in the safety, quality or efficacy of the biological for its intended use.

New subsection 9D(3B) provides that where a biological included in the Register under Part 3-2A ceases to be a biological because of a determination made by the Secretary under 32A(3) that the therapeutic good is not to be a biological for the purposes of the Act, the Secretary must move the entry relating to the therapeutic good to the relevant part of the Register. This would provide that where a therapeutic good is declared not to be a biological the Secretary must move it to that part of the Register for medical devices, registered goods or listed goods.

Item 16
This item amends subsection 9D(4) in relation to the movement of medical devices to another part of the Register where they are declared by the Secretary not to be medical devices under subsection 41BD(3) of the Act. Reference to the part of the Register for registered goods or that part for listed goods is replaced by this item with reference to whatever part of the Register is applicable, to reflect the new part of the Register for biologicals (items 55 and 60 refer).

Release of non-conforming biologicals in exceptional circumstances

Items 17 to 23 relate to the release of biologicals that do not conform to standards applicable to them, in exceptional circumstances.

These amendments include an exception to each of the relevant criminal offences and civil penalty provisions set out in sections 14 and 14A of the Act regarding importing, supplying or exporting therapeutic goods that do not comply with applicable standards.

Part 3-1 of the Act deals with standards for therapeutic goods that are not medical devices, and is intended to apply to biologicals.

Sections 14 and 14A of the Act set out, respectively, criminal offences and civil penalties for importing into, supplying in or exporting from, Australia, therapeutic goods that do not conform with a standard applicable to the goods (standards applying to therapeutic goods are determined by the Minister under section 10 of the Act).

It is intended to amend the Therapeutic Goods Regulations 1990 (the Regulations) to set out (among other changes relating to the Bill) a list of circumstances for the purposes of these exceptions to non-compliance with applicable standards,

For example, where a person who has Hepatitis C requires a skin graft urgently and conforming tissue of the patient's tissue type is not available, then the patient may agree to be treated with tissue that is also positive for the Hepatitis C virus and, thus, non-conforming.

While the tissue released in this situation would be non-conforming against the standards, the tissue, as a product, would be included in the Register and would be required to comply with the standards. Exceptional release recognises the varying nature of biological products and that in exceptional circumstances biologicals that would otherwise be required not to be supplied, as they do not meet the applicable standards required for inclusion in the Register, or the manufacturing standards may be clinically the best option available in critical circumstances.

Items 17 to 19
Items 17 to 19 provide for the exceptions to the application of the offence provisions.

Item 17 inserts new subsection 14(5A) to provide that the offence provision for importation of a therapeutic good set out in subsection 14(1), (2) or (4) does not apply if the good is a biological that is imported for exceptional release in accordance with the circumstances set out in the Regulations made for the purposes of this subsection.

This item includes a note that the heading to subsection 14(5) is amended to read 'Exceptions'. Both subsections 14(5) and (5A) are exceptions to specified offences under section 14.

Item 18 inserts a new subsection 14(9A) to provide that the offence provisions for supply of a therapeutic good set out in subsection 14(6), (7) or (9) do not apply if the good is a biological that is supplied in accordance with the exceptional release circumstances set out in the Regulations made for the purposes of this subsection.

Item 19 inserts a new subsection 14(13A) to provide that the offence provisions for export of a therapeutic good set out in subsection 14(10), (11) or (13) do not apply if the good is a biological that is exported for exceptional release in accordance with the circumstances set out in the Regulations made for the purposes of this subsection.

As new subsections 14(5A), (9A) and (13A) are exception provisions, the evidential burden for these new subsections rests with a defendant as set out under subsection 13.3(3) of the *Criminal Code 1995*.

An exception which places the evidential burden of proof on the defendant in this context is appropriate, as it would ultimately be the sponsor that would release (that is, import into, export from or supply in, Australia), a biological under the proposed exemption for exceptional release and who should have access to the information relating to the product and its properties.

It is intended that the Regulations supporting these provisions will require the sponsor to have received information about the use of biologicals that do not conform with applicable standards, and either notify the Secretary of this information after the biological is imported into or supplied in Australia, or provide the information in an application seeking approval to export the biological. Therefore, evidence in support of compliance with exceptional release circumstances set out in the Regulations can only be demonstrated by the defendant.

Items 20 to 22
These items amend section 14A which sets out civil penalties for importing, supplying or exporting goods that do not comply with the standards to provide that civil penalties are not to apply where non-conforming goods are biologicals that are imported, supplied or exported under exceptional release.

Item 20 inserts new subsection 14A(1A) to provide that the civil penalty provided under subsection 14A(1) does not apply where a non-conforming good is a biological that is imported under exceptional release circumstances set out in the Regulations.

Item 21 inserts new subsection 14A(2A) to provide that the civil penalty provided under subsection 14A(2) does not apply where a non-conforming good is a biological that is supplied under exceptional release circumstances set out in the Regulations.

Item 22 inserts new subsection 14A(3A) to provide that the civil penalty provided under subsection 14A(3) does not apply where a non-conforming good is a biological that is exported under exceptional release circumstances set out in the Regulations.

Item 23
This item inserts a new section 15AB at the end of Chapter 3, Part 3-1.

Subsection (1) provides that Regulations made for the purposes of new paragraphs 14(9A)(b) and 14A(2A)(b), criminal offence and civil penalty exemptions for exceptional release of biologicals, may also prescribe conditions to apply in relation to the supply of a biological that occurs after the circumstances prescribed for those paragraphs have occurred.

This provision would enable Regulations to prescribe, for example, reporting of any adverse events following the supply of a non-conforming biological under exceptional release circumstances.

Subsection (2) provides that the conditions prescribed by the Regulations under subsection (1) must apply only to the person supplying the biological, that is the sponsor of the biological.

Subsection (3) provides that a person commits an offence with a maximum penalty of 60 penalty units if the person breaches any of the conditions referred to in subsection (1).

Item 24
This item inserts new section 15B in Chapter 3, Part 3-2, which provides for the registration and listing of medicines and therapeutic devices.

Subsection (1) provides that subject to the other subsections, Part 3-2A does not apply to a biological on and after the commencement of the section.

Subsection (2) provides that where a biological is included in the Register as a registered or listed good under Part 3-2 immediately before the commencement of this section Part 3-2 is to continue to apply to that biological until it is included in the Register under Part 3-2A. This will ensure a smooth transition for biologicals from being regulated as registered or listed goods to being regulated as biologicals under the Act.

Subsection (3) provides that where an application is made to register or list a therapeutic good that is a biological (new section 32A refers) before the commencement of this section, and the application was not finally determined or had not been withdrawn, then Part 3-2 is to continue to apply to the application on or after the commencement of the section until the earliest of:

- if the application is successful, inclusion in the Register under Part 3-2A;
- if the application is unsuccessful, the time when it is finally determined;
- the time when the application is withdrawn; or
- the time the application lapses.

This will enable an affected application to be considered and evaluated, where appropriate, under Part 3-2. If successful the biological would then be included in the Register as either a registered or listed good. At that time it is then able to be transferred to that part of the Register for biologicals (new section 32DN refers).

Subsection (4) defines ***finally determined*** for the purposes of subsection (3) and provides that an application is finally determined when the application and, if applicable, any applications for reviews and appeals arising out of it have been finally determined or disposed of.

Subsections (5) and (6) set out the transitional arrangements.

Subsection (5) provides that Part 3-2 of the Act applies to a biological on and after the commencement of the section in relation to things done or omitted to be done in relation to the biological before the commencement of the section.

Subsection (6) provides that if Part 3-2 continues to apply to a biological during a period described in subsection (2) or (3), then Part 3-2 also applies to the biological after the end of that period in relation to things done, or omitted to be done, in relation to the biological during that period.

For example, where:

- an application is made for the inclusion of a biological in the register under Part 3-2 prior to commencement of the section, and
- it is found to have contained false information after the biological is included in the Register as a registered good (and then transferred to that Part for biologicals);

the offence and civil penalty provisions under Part 3-2 that relate to the provision of false and misleading information in relation to the application for registration or listing would apply to

the applicant for the inclusion of the goods (the biological) in the Register under Part 3-2 of the Act.

Item 25
This item inserts a new Part 3-2A after Part 3-2 in Chapter 3 of the Act. The new Part 3-2A provides for the separate regulatory arrangements for biological therapeutic goods through the inclusion of new sections 32 to 32JM.

PART 3-2A - Biologicals

Division 1 - Preliminary

Section 32 – What this Part is about
This section provides an explanation of new Part 3-2A.

Section 32A – Meaning of *biological*
This section provides a definition of ***biological*** for the purposes of the Act.

Subsection (1) sets out the general definition of a biological as a thing that comprises, contains or is derived from human cells or tissues and is represented in any way to be, or is likely to be taken to be, for a therapeutic use as set out in subparagraphs (1)(b)(i) to (v).

Subsections (2) and (3) allow the Secretary to make legislative instruments clarifying the application of the definition.

Subsection (2) empowers the Secretary, by legislative instrument, to specify a thing as other than a thing that comprises, contains or is derived from human cells or tissues as a biological, as long as it is represented or is likely to be taken to be for therapeutic use.

Subsection (3) empowers the Secretary, be legislative instrument, to declare that a thing is not a biological for the purposes of the Act.

Section 32AA – Biological classes
This section provides that the regulations may prescribe different classes of biologicals. 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 biologicals. It is expected that the regulations will specify four classes of biologicals ranging from lower risk (Class 1) to higher risk (Class 4).

The Part provides that the application and assessment criteria for Class 1 biologicals (lower risk biologicals) would be different from that for other classes of biologicals (new sections 32DA, 32DD and 32DE refer).

Section 32AB – When biological classes are separate and distinct from other biologicals
This section sets out when a biological is to be taken to be separate and distinct from another biological for the purpose of identifying if a separate entry or inclusion in the Register under Part 3-2A is required.

Subsection (1) provides that the regulations may prescribe the circumstances in which a biological included in a specified class of biologicals is separate and distinct from other biologicals.

Subsection (2) provides that regulations may make different provisions in relation to the different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

For example, the regulations may specify that a particular Class 1 biological is separate and distinct from another Class 1 biological if it has a different sponsor or manufacturer.

The note explains that where a biological is included in the Register with other biologicals and it changes so that it has become separate and distinct from the biologicals as included in the same entry in the Register when it was approved for entry in the Register, then the Secretary may cancel the biological's entry in the Register. The person in respect of whom the biological was included in the Register may then apply for the biological to be included in the Register under a new entry reflecting the changed characteristics of the biological (new sections 32DA and 32DD refer).

Division 2 – Main criminal offences and civil penalties

The main criminal offence and civil penalty provisions and penalty levels relating to dealing in biologicals set out in this division (and the subsidiary offences in Divisions 3, 4, 5 8 and 9) are consistent with those established under the Act in regard to other therapeutic goods (medicines, therapeutic devices and medical devices). This is to ensure a consistent approach to regulation of conduct in regard to dealings in therapeutic goods in Australia.

References in the offence provisions under this Part to a person include both a natural person and a corporate person. The penalty for a corporate person is five times the number of penalty units set out in the offence.

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.

This tiered regime of criminal offences tailors penalties to criminal conduct so that more serious offences resulting in, or that are likely to cause, harm or injury will attract heavier

criminal sanctions. The penalties for offences with aggravating elements are significantly higher than the proposed offences without aggravating elements – as is the case with existing corresponding offences already set out in the Act. This reflects the fact that breaches of these provisions have resulted in adverse effects on people's health or will pose a serious and direct threat to public health and safety.

The table below sets out those provisions where the tiered approach applies:

Proposed new provision	**Offence**	**Provision(s) in the Act upon which provision based**
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 the Register	Subsections 21A(5) to (8)
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)

The high penalty levels that apply in relation to the relevant fault-based offences with the aggravating element are proposed because these offences directly link the relevant conduct relating to the offence with adverse consequences resulting from the regulated conduct (either the conduct has, will or would result in harm or injury to a person).

The maximum level of penalty for a criminal offence in the Bill, being 5 years imprisonment or 4,000 penalty units, is proportionate to the harm or injury resulting from the breach of the relevant proposed regulatory requirements and the penalty level imposed under the corresponding offence which features no aggravating element and is consistent with equivalent offences in Part 3-2 and Chapter 4 of the Act.

The maximum penalty level for the proposed strict liability offences included in the Part with an aggravating element is 2,000 penalty units. 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.

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.

The fault-based offences in the Part will not apply where harm or injury to a person is caused by reasons other than a breach of the regulatory requirements relating to biologicals. The fault-based offences that include an appropriate aggravating element have maximum penalties that exceed the applicable maximum penalties for the relevant offence relating to the same conduct but which does not contain the specified aggravating element.

In addition to the tiered criminal offences discussed above, the Part includes a range of civil penalties that may apply as an alternative sanction to corresponding criminal offences directed at ensuring the safety of biologicals for use by the community. The civil penalty provisions are based upon, and are largely consistent with, existing civil penalty provisions included in the Act in 2006.

The focus of a civil penalty scheme is generally on the regulation of commercial activity and is appropriate for the regulation of commercial activities involving therapeutic goods, particularly as the Act mainly regulates incorporated companies and subsidiaries of multinational companies engaged in commercial operations.

The inclusion of a civil penalty regime into the Act in respect of biologicals will ensure consistency in the Act in relation to the treatment of biologicals compared with the treatment of other therapeutic goods, and ensure that the enforcement options available to the Secretary will deter non-compliance with regulatory requirements designed to protect public health and safety in relation to therapeutic goods.

A civil penalty regime is also appropriate to enable sponsors and manufacturers (particularly those who have substantial power over essential therapeutic goods) to be heavily fined for serious breaches of the Act where other sanctions may not be as effective or appropriate in the circumstances.

Pecuniary penalties for the contravention of civil penalty provisions need to be high enough to ensure that they act as an effective deterrent in order to secure future compliance with regulatory requirements. The penalty levels proposed in the Part in this regard are in accordance with existing provisions in the Act, and penalties in other legislation such as the *Environmental Protection and Biodiversity Convention Act*, the *Trade Practices Act 1974*, and the *Australian Securities and Investments Commission Act 2001*. The maximum civil penalty will be 5,000 penalty units ($550,000) for an individual and 50,000 penalty units ($5.5 million) for a body corporate. The courts will always have the discretion to impose lesser penalties than the maximum amount specified in the legislation, to reflect the level of gravity of the relevant unlawful conduct. The pecuniary penalty ordered by the court is payable to the Commonwealth, and the Commonwealth can enforce the order as if it were a judgment of the court.

The table below lists the civil penalty provisions in the Part, a brief description of the conduct to which they apply, the relevant maximum penalty, the corresponding criminal offence (where applicable) and the existing provision in the Act upon which each civil penalty provision is based (where applicable).

Civil penalty provision	**Relevant conduct to which provision relates**	**Maximum penalty**	**Corresponding criminal offence provision in the Bill**	**Provision in the Act upon which civil penalty provision based**
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 body corporate	N/A	Subsection 19D(4)
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
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 matters such as formulation and design of a biological that is false or misleading	5,000 penalty units for an individual 50,000 penalty units for a body corporate	Section 32JB	NA
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

Provisions dealing with requirements regarding the commencement of civil proceedings and other administrative aspects of civil penalties are set out in Part 5A-1 of the Act.

Sections 42YJ and 42YK, including the regulations made under them, which provide that infringement notices may be issued in place of criminal and civil penalty proceedings, will apply to the criminal offence and civil penalty provisions set out in this new Part to the Act.

Enforceable undertakings (42YL), the alternative verdict provisions under section 53A, the search and seizure provisions under Part 6-2 of the Act, Part 5A-1 of the Act and other general enforcement measures set out in the Act will also apply to biologicals.

Section 32B – What this Division is about
This section outlines the main criminal offences and civil penalties relating to importing, exporting, manufacturing, supplying and using biologicals in contravention of requirements in the Act.

Section 32BA – Criminal offences for importing a biological
This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person imports a biological into Australia for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for import of the biological into Australia for special and experimental uses, under subsection 32CK(1),
  - the subject of an approval held by the person for import of the biological into Australia to substitute for a biological included in the Register that is in short supply or unavailable, under section 32CO, or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Subsection (1) provides an offence where a person imports a biological (as set out in the list above) and the use of that biological has or will result in harm or injury to a person, or if it were to be used it would do so. The maximum penalty for a breach of this subsection is 5 years imprisonment or 4,000 penalty units, or both.

This subsection includes an explanatory note that a jury may acquit a person of an offence under subsection (1) and instead convict the person of an offence against subsection (4).

The penalty for an offence against this subsection is the same as that imposed for exportation, manufacture or supply of biologicals that are not in the Register, exempted, approved or where the person has been exempted or approved in relation to the biological.

Subsection (2) provides an offence where a person imports a biological (as set out in the list above) that, were it to be used, would be likely to result in harm or injury to any person, with a maximum penalty of 2,000 penalty units. Subsection (3) explains that an offence against subsection (2) is an offence of strict liability.

Subsection (4) provides an offence if a person were to import a biological (as set out in the list above) regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Subsections (5) and (6) provide defences to the above importation offences and are explained below.

Section 32BB – Criminal offences for exporting a biological
This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person exports a biological from Australia for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person to export from Australia the biological for special and experimental uses, under subsection32CK(1), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

The offences, penalties and defences provided under this section are consistent with those provided in relation to importation and exportation of biologicals.

Subsection (1) provides that it is an offence for a person to manufacture a biological (as set out in the list above) and the use of that biological has or will result in harm or injury to a person, or if it were to be used it would do so. The maximum penalty for a breach of this subsection is 5 years imprisonment or 4,000 penalty units.

The penalty for an offence against this subsection is the same as that imposed for importation, manufacture or supply of biologicals that are not in the Register, exempted, approved or where the person has been exempted or approved in relation to the biological.

This subsection includes an explanatory note that a jury may acquit a person of an offence under subsection (1) and instead convict the person of an offence against subsection (4).

Subsection (2) provides an offence where a person exports a biological (as set out in the list above) that were it to be used, would be likely to result in harm or injury to any person, with a maximum penalty of 2,000 penalty units. Subsection (3) explains that an offence against subsection (2) is an offence of strict liability.

Subsection (4) provides that it would be an offence against this subsection if a person were to export a biological (as set out in the list above) regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Subsections (5) and (6) provide defences to the above exportation offences and are explained below.

Section 32BC – Criminal offences for manufacturing a biological
This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person manufactures a biological for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes, or

- the person has been exempted under subsection 32CA(1) in relation to the biological.

The offences, penalties and defences provided under this section mirror those provided in relation to importation to recognise Australia's global public health and safety responsibility in relation to export of therapeutic goods.

Subsection (1) provides that it is an offence for a person to export a biological (as set out in the list above) and the use of that biological has or will result in harm or injury to a person, or if it were to be used it would do so. The maximum penalty for a breach of this subsection is 5 years imprisonment or 4,000 penalty units or both.

The penalty for an offence against this subsection is the same as that imposed for importation, exportation or supply of biologicals that are not in the Register, exempted, approved or where the person has been exempted or approved in relation to the biological.

This subsection includes an explanatory note that a jury may acquit a person of an offence under subsection (1) and instead convict the person of an offence against subsection (4).

Subsection (2) provides an offence where a person manufactures a biological (as set out in the list above) that were it to be used, would be likely to result in harm or injury to any person, with a maximum penalty of 2,000 penalty units. Subsection (3) explains that an offence against subsection (2) is an offence of strict liability.

Subsection (4) provides that it would be an offence against this subsection if a person were to manufacture a biological (as set out in the list above) regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Subsections (5) and (6) provide defences to the above manufacturing offences and are explained below.

Section 32BD – Criminal offence for supplying a biological
This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person supplies a biological for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for supply in Australia of the biological for special and experimental uses, under subsection 32CK(1),
  - the subject of an authority held by a medical practitioner for the biological, under subsection 32CM(1),
  - the subject of an approval held by the person for supply in Australia of the biological to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Subsection (1) provides that it is an offence for a person to supply a biological (as set out in the list above) and the use of that biological has or will result in harm or injury to a person, or if it were to be used it would do so. The maximum penalty for a breach of this subsection is 5 years imprisonment or 4,000 penalty units or both.

The penalty for an offence against this subsection is the same as that imposed for importation, exportation or manufacture of biologicals that are not in the Register, exempted, approved or where the person has been exempted or approved in relation to the biological.

This subsection includes an explanatory note that a jury may acquit a person of an offence under subsection (1) and instead convict the person of an offence against subsection (4).

Subsection (2) provides an offence where a person supplies a biological (as set out in the list above) that were it to be used, would be likely to result in harm or injury to any person, with a maximum penalty of 2,000 penalty units. Subsection (3) explains that an offence against subsection (2) is an offence of strict liability.

New subsection (4) provides that it would be an offence against this subsection if a person were to supply a biological (as set out in the list above) regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Subsections (5) and (6) provide defences to the above supply offences and are explained below.

Defences

Sections 32BA to 32BD set out a defence (at subsections 32BA(5), 32BB(5), 32BC(5) and 32BD(5)) to any of the offences set out in those sections if the defendant proves that the defendant was not the sponsor of the biological at the time of the relevant importation, exportation, manufacture or supply, as the case may be.

The defendant will bear the legal burden of establishing the defence on the balance of probabilities. The defendant, for example, must prove that there was an agency or other arrangement and that the defendant did not act as a principal in unlawfully importing, exporting, manufacturing or supplying biologicals.

The same defence applies to the existing equivalent offences applying to medicines and therapeutic devices (subsection 19B(5)) and medical devices (subsection 41MI(6)).

The legal burden is borne by the defendant in relation to this defence because the existence of a principal-agent relationship can only be conclusively demonstrated by the parties involved, and is not apparent to the Commonwealth.

Exceptions

Each of subsections 32BA(6), 32BB(6) 32BC(6) and 32BD(6) set out an exception to the offence attracting the highest maximum penalty in respect of each of importing, exporting, manufacturing and supplying biologicals in breach of the subsections (subsections 32BA (1), 32BB (1), 32BC (1) and 32BD (1)). The exception will apply if harm or injury did not, or will not, or would not, directly result from the quality, safety or efficacy of the biological, or

a matter relating to the labelling or packaging of the biological or the improper use of the biological.

As these new subsections are exception provisions, the evidential burden for these new subsections rests with a defendant as set out under subsection 13.3(3) of the *Criminal Code 1995*.

An exception which places the evidential burden of proof on the defendant in this context is appropriate, as it would ultimately be the person introducing a biological into the market who should have access to the information relating to the product and its properties.

These exceptions are based upon and are consistent with exceptions set out in existing subsections 19B(6) and 41MI(7) of the Act.

Section 32BE – Notice required to adduce evidence in support of exception to offences
Section 52BE allows a defendant to provide a pre-disclosure notice of evidence in support of an exception to an offence relating to the importation, exportation, manufacture or supply of goods that are not included in the Register prior to the defendant being committed for trial or prior to a hearing by a court of summary jurisdiction. This is provided under section 32BE and is consistent with a similar provision for registered and listed therapeutic goods under section 19C of the Act.

The pre-disclosure requirement is intended to provide the prosecution with a more adequate method of assessing the evidence or defence relied upon by the defendant. The time is needed because the regulator will be required to obtain information about the goods being unlawfully supplied, manufactured, imported or exported, as this would be information the regulator would not normally hold.

Section 52BE sets out requirements for defendants intending to produce evidence in support of a defence (provided under subsection 32BA(6), 32BB(6), 32BC(6) or 32BD(6)) against an offence (under subsection 32BA(1), 32BB(1), 32BC(1) or 32BD(1)) for the importation, exportation, manufacture or supply of a biological where the use of the biological has, will or would result in harm or injury.

Subsection (1) provides that where a defendant is committed for trial for an offence set out above, or the offence is to be heard and determined by a court of summary jurisdiction, the committing magistrate or the court (as relevant) must inform the defendant of the requirements of this section for adducing evidence in support of the defence and cause a copy of this section to be given to the defendant.

Subsection (2) provides that the defendant must not cite evidence in support of the exception under subsection 32BA(6), 32BB(6), 32BC(6) or 32BD(6) unless they gave a notice to the Director of Public Prosecutions, in accordance with subsection (6), setting out the details of the exception more than 21 days before either the trial begins (if paragraph (1)(a) applies or more than 21 days before the hearing of the offence begins (if paragraph (1)(b) applies).

Subsection (6) sets out that a notice under this section must be given in writing to the Director of Public Prosecutions (DPP) and be delivered to or left at the Office of the DPP or sent by certified mail to the DPP at an office of the DPP. Subsection (7) defines the ***Director of Public Prosecutions*** in relation to the *Director of Public Prosecutions Act 1983*.

Subsection (3) provides that a defendant must not call any other person to give evidence in support of the exception claimed unless the requirements set out in subsection (3) are met or the court grants leave to do so.

Paragraph (3)(a) sets out that, unless the court grants leave to do so, a defendant must include in the notice under subsection (2) the name and address of the person they seek to call on to give evidence or if these details are not known by the defendant at the time of giving the notice include in the notice any information the defendant has that might be of material assistance in finding the person.

Paragraph (3)(b) requires that where the name and address of the person are not included in the notice the court must be satisfied that the defendant took all reasonable steps before and after giving the notice to ascertain these details.

Further, paragraph (3)(c) provides that if the defendant, after giving the notice, ascertains the name and address of the person, or information that might be of material assistance in finding the person, they seek to call on to give evidence in support of the exception the defendant must immediately give notice of these details or information to the DPP in accordance with subsection (6).

Paragraph (3)(d) sets out the requirements for a defendant where the defendant is informed by, or on behalf of, the prosecutor that the person they advised in the notice has not been found by the name or at the address given by the defendant in the notice. In such circumstances the defendant must comply with the requirements set out in subparagraphs (3)(d)(i) and (ii). Subparagraph (i) provides that the defendant must immediately give notice to the DPP of any information they have that might be of material assistance in finding the person. However, where the defendant does not have that information at that time but later receives such information subparagraph (ii) requires the defendant to immediately give notice to the DPP of that information when the defendant receive it.

The purpose of the above provisions is to ensure that the DPP is able to receive all pertinent information in relation to the offence or the defence to it.

Subsection (4) explains that where a notice is given under this section on behalf of the defendant by the defendant's legal counsel, the notice is taken to have been given with the authority of the defendant, unless otherwise proved. This clarifies that a notice may be given on behalf of a defendant by their legal counsel.

Subsection (5) explains that evidence tendered to the court to disprove the exception claimed by the defendant can be given either before or after the evidence is given to support the exception.

Section 32BF – Civil penalties for importing, exporting, manufacturing or supplying a biological

Section 32BF sets out civil penalties as alternative sanctions to the offences under sections 32BA to 32BD for importing, exporting, manufacturing or supplying a biological by a person where the biological is not included in the Register in relation to the person or where certain specified exemptions, approvals or authorities do not apply in relation to the person or the biological in question. These civil penalty provisions do not apply if the person proves that

he or she was not the sponsor of the biological at the time of the importation, exportation, manufacture or supply, as the case may be.

Importation
Subsection (1) provides that a person contravenes this subsection if the person imports a biological into Australia for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for import of the biological into Australia for special and experimental uses, under subsection32CK(1),
  - the subject of an approval held by the person for import of the biological into Australia to substitute for a biological included in the Register that is in short supply or unavailable, under section 32CO, or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Exportation
Subsection (2) provides that a person contravenes this subsection if the person exports a biological from Australia for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person to export from Australia the biological for special and experimental uses, under subsection 32CK(1), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Manufacture
Subsection (3) provides that a person contravenes this subsection if the person manufactures in Australia a biological for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes, or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Supply
Subsection (4) provides that a person contravenes this subsection if the person supplies a biological in Australia for use in humans and none of the following apply:

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for supply of the biological in Australia for special and experimental uses, under subsection32CK(1),

  - the subject of an authority held by a medical practitioner for the biological, under subsection 32CM(1),
  - the subject of an approval held by the person for supply in Australia of the biological to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Section 32BF is based upon existing sections 19D and 41MIB of the Act, and the maximum civil penalties specified in proposed subsections 32BF(1)-(4) of 5,000 penalty units for an individual and 50,000 for a body corporate are the same as in those existing provisions.

Subsection (5) provides an exception to the above civil penalties where the person proves that they were not the sponsor of the biological at the time of the importation, exportation, manufacture or supply. As with the exceptions to the criminal offence provisions for importation, exportation, manufacture and supply of biologicals provided under subsections 32BA(5), 32BB(5), 32BC(5) and 32BD(5), the person must prove that they were not the sponsor as the Commonwealth will not be in possession of information regarding this.

Subsection (6) provides that a person contravenes that subsection if:
- a biological is included in the Register in relation to the person; and
- the biological is of a kind prescribed by the regulations for the purposes of proposed subsection 32BF(6); and
- the person supplies the biological in Australia; and
- the biological number of the biological is not set out on the label of the biological in the prescribed manner.

The maximum penalty for contravention is 200 penalty units for an individual and 2,000 penalty units for a body corporate. Subsection 32BF(6) is based upon and applies the same maximum penalty level as existing subsection 19D(4) of the Act.

The subsection provides that the regulations may prescribe kinds of biologicals that will require the biological number to be set out on the label. This is because there may be kinds of biologicals where it would be not be appropriate or possible to set the number out on the label or to affix a label to the biological. (This may apply, for example, where the biological consists of a small number of cells stored in a small container and where this is supplied by a hospital tissue bank directly to a doctor for immediate use in a patient.)

Section 32BG – Criminal offence and civil penalty relating to a failure to notify the Secretary about manufacturing

This section sets out the criminal offence and civil penalty provisions applying to sponsors who import, export, manufacture or supply biologicals for use in humans and do not properly notify the Secretary (before the import, export, manufacture or supply) of either or both the manufacturer of the biological or the premises used in the manufacture of the biological, and the biologicals or sponsor are not otherwise exempt under subsections 32CA(1) or (2).

Subsection (1) provides that failure to properly notify the Secretary is a criminal offence and attracts a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both. The penalty is set to reflect the risk posed to public health and safety where biologicals are manufactured at sites that have not been appropriately assessed and approved to ensure

quality and safety of the manufactured biological. This provision is based upon, and is consistent with (including in relation to maximum penalty levels), existing subsection 20(1B) of the Act.

Subsection (2) provides that a civil penalty applies where the sponsor fails to notify the Secretary in the same circumstances. The maximum civil penalty is 5,000 penalty units and for a body corporate the maximum penalty is 50,000 penalty units.

Subsection (3) defines ***properly notified*** in relation to notifying the Secretary of the manufacturer or the manufacturing premises as occurring when the sponsor of the biological nominates the manufacturer or the manufacturing premises in the application submitted for the inclusion of the biological in the Register (new sections 32DA and 32DD refer) or where the sponsor subsequent to inclusion in the Register informs the Secretary in writing that the manufacturer or the manufacturing premises is the manufacturer or are the premises, respectively, for the biological. For example, where the sponsor of the biological terminates the services of one manufacturer and agrees by contract to have the manufacture of the biological provided for by another manufacturer.

The note at the end of the new section explains that subsections 32EA(4) and (5) provide conditions for the inclusion of a biological in the Register relating to manufacture.

Section 32BH – Criminal offence relating to wholesale supply
This section provides that it is an offence if a person (who may or may not be the sponsor of the biological) supplies a biological to a person who isn't the ultimate consumer, unless one of the following apply:

- the biological is:
  - included in the Register,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for supply in Australia of the biological for special and experimental uses, under subsection32CK(1),
  - the subject of an authority held by a medical practitioner for the biological, under subsection 32CM(1),
  - the subject of an approval held by the person for supply in Australia of the biological to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

The penalty for an offence against this section is 120 penalty units to prevent wholesale supply of biologicals that do not conform to the requirements set out under the Act. Section 32BH is based upon existing section 21 of the Act and has the same maximum penalty level.

Section 32BI – Criminal offence for using a biological not included in the Register
This section establishes a tiered criminal offence regime (see pages 33 to 35) for using a biological in the treatment of another person or solely for experimental purposes in humans where none of the following apply:

- the biological is:
  - included in the Register,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the person uses the biological in accordance with an approval for special and experimental uses under subsection32CK(1),
  - the person uses the biological in accordance with any applicable conditions prescribed by the regulations relating to the use of the biological for experimental purposes in humans, made for the purposes of section 32CL,
  - the person uses the biological in accordance with an authority issued to a medical practitioner under subsection 32CM(1),
  - the subject of an approval to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

Subsection (1) provides that it is an offence against this subsection if, in the above circumstances, a biological is used in the treatment of another person or solely for experimental purposes in humans and its use has resulted in or will result in harm or injury to the person treated or humans involved. The penalty for an offence against this subsection is imprisonment for 5 years or 4,000 penalty units or both.

Subsection (2) provides that it is an offence against this subsection if, in the above listed circumstances, the use of the biological is likely to result in harm or injury to the person being treated or the human s involved in the research, with a maximum penalty of 2,000 penalty units. Subsection (3) explains that subsection (2) is an offence of strict liability.

Subsection (4) provides that it would be an offence against this subsection if a person were to use a biological (as set out in the list above) regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 500 penalty units.

Section 32BJ – General criminal offences relating to this Part
This section provides three general offences in relation to biologicals.

Subsection (1) provides that it is an offence against this subsection if a person applies a number that is purported to be the ***biological number*** to the container, package or label of a biological and that number is not the biological number for that biological as defined under subsection 3(1) (item 2 refers). The penalty for an offence against this subsection is 60 penalty units.

The purpose of this offence provision is to prevent biologicals that are not included in the Register being passed off as included in the Register by the application to the biological of a number purporting to be the biological number, such as counterfeit biologicals. The offence provision is also aimed to ensure that only the correct biological number for a biological is applied to enable correct identification of biologicals such as to support recall of biologicals by use of this unique identifier.

Subsection (2) explains that a ***number*** can include any combination of numbers, letters or symbols. For example, medicines registered under the Act carry a number that has the suffix

'Aust R' and medicines listed under the Act the suffix 'Aust L' to indicate that the sequence of numbers following the suffix represent the unique registration or listing number for the medicine in the Australian Register of Therapeutic Goods. A similar numbering system will be used to identify biological therapeutic goods.

Subsection (3) provides that a person commits an offence if they advertise, by any means, a biological that is included in the Register for an indication that is not the indication accepted for its inclusion in the Register. The maximum penalty is 60 penalty units, consistent with existing subsection 22(5) and section 41ML applying to advertising of medicines and therapeutic devices, and medical devices, respectively.

This is necessary to ensure appropriate information is provided to the public to support safe, effective and correct use of biologicals. The amendment will also prevent a sponsor requesting that another person advertise their biological on their behalf for an indication for which the biological has not been shown to be safe and effective.

Subsection (4) provides that a person commits an offence if they claim, in any way, that they or another person can arrange the supply of a biological that does not meet any of the following criteria (ie: that does not comply with the Act):

- the biological is:
  - included in the Register in relation to the person,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval held by the person for supply in Australia of the biological for special and experimental uses, under subsection 32CK(1),
  - the subject of an authority held by a medical practitioner for the biological, under subsection 32CM(1),
  - the subject of an approval held by the person for supply in Australia of the biological to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- the person has been exempted under subsection 32CA(1) in relation to the biological.

The penalty for making such a claim is 60 penalty units to deter people from claiming they are able to supply biologicals that are not approved, exempted or otherwise comply with the Act irrespective of if the person does or intends to actually supply the biological.

Section 32BK – Civil penalty for making misrepresentations about biologicals

This section provides that a person contravenes it if they make a representation where this is false or misleading in respect of one or more of the following:

- they represent the biological as being:
  - included in the Register,
  - exempted under subsection 32CA(2),
  - exempted under section 32CB, for emergency purposes,
  - the subject of an approval for supply in Australia of the biological for special and experimental uses, under subsection32CK(1),
  - the subject of an authority under subsection 32CM(1),

- the subject of an approval for supply in Australia of the biological to substitute for a biological included in the Register that is in short supply or unavailable, under subsection 32CO(1) or (2), or
- they represent that a person is exempt under subsection 32CA(1) in relation to the biological.

The maximum civil penalty for a contravention of this section is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate. The penalty level reflects the potential harm from such false and misleading representations which may be involved in activities such as sale of counterfeit biologicals that are not shown to be safe or effective. Section 32BK is based upon and has the same maximum penalty as existing subsection 21B(3) of the Act.

Division 3 – Exemptions

This division sets out the circumstances where biologicals and persons importing, exporting, manufacturing, supplying or using them may be exempted from certain requirements of the Act to enable access and availability in emergency, or other high need circumstances, where this may not otherwise be possible under the requirements of the Act.

Subdivision A – Preliminary

Section 32C – What this Division is about
This section outlines the four kinds of exemptions to certain requirements of the Act that are provided for under this Division in relation to biologicals and persons importing, exporting, manufacturing, supplying or using them.

Subdivision B – Exempting biologicals under the regulations

Section 32CA – Exempt biologicals
This section provides that regulations may be made to exempt specified biologicals, or specified persons in relation to biologicals, from the requirements, under Division 4, for the inclusion in the Register of biologicals for use in humans.

Subsection (1) provides that the regulations may exempt specified people or classes of people, in respect of certain specified biologicals or classes of biologicals, from the requirements under Division 4. For example the regulations may exempt persons who are involved in developing new biological products for use in humans, to the extent necessary to enable such research and development work. If the person later wishes to use the biologicals for experimental purposes in humans to then generate the data necessary to make an application for the biological to be included in the Register, the person would need to seek and receive an exemption for this purpose under new section 32CK.

Subsection (2) provides that regulations may be made to exempt certain specified biologicals or classes of biologicals from the requirements of Division 4. For example the regulations may exempt imported biologicals that are provided to the TGA as a sample that is required to be provided to the TGA as part of an application for inclusion in the Register.

Subsection (3) explains that an exemption under this section may be subject to conditions set out in the regulations. For example, the regulations may prescribe that a biological exempted

under subsection (2) is not to be manufactured in quantities above those required for the purposes of seeking approval for inclusion in the Register under new sections 32DA and 32DD.

Subsection (4) provides that a person commits an offence if they breach a condition imposed on an exemption granted under this section. The maximum penalty for an offence against this subsection is 60 penalty units.

Subsection (5) provides that if the regulations revoke an exemption previously applicable under the regulations, the regulations are to specify the date on which the revocation is to take effect which is to be no sooner than 28 calendar days after the day on which the regulations which revoke the exemption take effect.

Subdivision C – Exempting biologicals to deal with emergencies

Section 32CB – Minister may make exemption

The purpose of this section is to provide that biologicals and classes of biologicals which are not included in the Register can be exempted by the Minister from the requirements to be included in the Register under Division 4 so they are able to be stockpiled or released for use in emergencies. This provision reflects sections 18A and 41GS of the Act applying to medicines, therapeutic devices and medical devices.

Subsection (1) provides that the Minister may, by writing, exempt specified biologicals from the operation of Division 4 relating to the requirements regarding inclusion in the Register. This will enable biologicals to be stockpiled for release in emergency circumstances. For example, this provision may be used to stockpile biologicals which are currently not available in Australia or for which no person has applied to have the biological included in the Register, but where there is a public health imperative to import that biological to enable that biological to be included in the stockpile.

Subsection (2) provides that the Minister may make an exemption under subsection (1) only if the Minister is satisfied that it is in the national interest to make the exemption so that:

- the biologicals may be stockpiled as quickly as possible to prepare for a potential threat to public health that may be caused by a possible future emergency situation, or
- the biologicals can be made available urgently in Australia to respond to an actual threat to public health caused by an emergency that has occurred.

Subsection (3) provides that an exemption made under subsection (1) comes into force either on the day the exemption is made or at a latter date if specified in the exemption. Subsection (4) provides that an exemption remains in force either until the date specified in the exemption or unless revoked earlier than that date. The note explains that new section 32CD deals with variations to and revocation of exemptions provided under this Part including exemptions given under this section for emergency purposes.

Subsection (5) provides that if a biological that is exempted under subsection (1) for emergency purposes becomes included in the Register as a result of an application being made and approved (Division 4 refers) then it ceases to be exempted under this section. The biological remains able to be included in the national stockpile and made available in cases of

emergency; this subsection simply reflects that an exemption is no longer required to enable this to occur.

Subsection (6) explains for the benefit of readers that an exemption provided under subsection (1) is not a legislative instrument for the purposes of the *Acts Interpretation Act 2003*. A decision under this section is reviewable under section 60 of the Act.

This is because if the exemption were in the form of a legislative instrument this would make known publicly those biologicals exempted for inclusion in the national stockpile. For national security reasons this would pose a serious public health risk as it is necessary for the contents of the national stockpile to remain confidential to ensure that would-be bio-terrorists are not able to find out what preparations Australia has made for dealing with possible bio-terrorist acts. This aligns with the provisions under sections 18A and 41GS for the emergency stockpiling of medicines, therapeutic devices and medical devices.

Section 32CC – Conditions of exemptions
This section provides that conditions may be applied in relation to the exemption given under section 32CB for emergency purposes.

These may include, for example, conditions about where the biologicals are to be sourced, who may import, manufacture, supply or export the biologicals and to whom they may be supplied, particular storage, disposal and security requirements, requirements as to record keeping for tracking purposes or any matter the Minister thinks appropriate in a particular exemption. The breach of a condition does not affect the exempt status of the biological covered by an exemption.

The note under the section explains that criminal offences and civil penalties apply for breach of a condition of exemption and these are set out under sections 32CH and 32CI.

Conditions may be revoked, varied or added to after an exemption has been made (section 32CD, below, refers).

Section 32CD – Variation or revocation of exemption
This section empowers the Minister to, by writing, vary or revoke an exemption made under section 32CB or conditions applied under section 32CD to such an exemption.

Subsection (1) empowers the Minister to vary an exemption made under section 32CB to remove specified biologicals, or classes of biologicals, from the exemption. For example, where an exemption includes more than one biological and one or more of those is no longer required in the national emergency stockpile the Minister may vary the exemption by removing the biological(s) that are no longer needed.

Subsection (2) empowers the Minister to revoke an exemption in full.

Subsection (3) empowers the Minister to vary, revoke or impose new conditions on an exemption given under section 32CB.

Subsection (4) explains that if the Minister states in the variation or revocation written instrument that a variation or revocation is necessary to prevent imminent risk of death, serious injury or serious illness then the variation or revocation takes effect immediately. In

any other case it takes effect on a day specified by the Minister in the variation or revocation and this day is not to be sooner than 28 days after the variation or revocation is made by the Minister. This ensures that serious risks to public health can be responded to quickly.

Section 32CE – Informing persons of exemptions etc.
This section requires that the Minister take reasonable steps to give a copy of any written instrument relating to the exemption and any variation or revocation of the exemption to all persons who are the subject of a condition under subsection 32CC(c) in relation to the importation, exportation, manufacture or supply of the exempted biological(s).

Section 32CF – Notification and tabling
Subsection (1) provides that:

- an exemption made because of paragraph 32CB(2)(b); or
- an variation or revocation of such an exemption under section 32CD

must be published by the Secretary in the *Gazette* within 7 days after the exemption, variation or revocation is made.

Subsection 32CF(2) provides that the Minister must cause a document setting out particulars of an exemption made because of paragraph 32CB(2)(b) or a variation or revocation of such an exemption under section 32CD to be tabled in each House of the Parliament within five sitting days of that House, after the exemption, variation or revocation is made.

Failure to publish or table does not invalidate the exemption, variation or revocation.

Section 32CG – Disposal of unused biologicals
This section empowers the Secretary to arrange for the disposal of unused biologicals where the exemption under section 32CB ceases to have effect (for example, where the biologicals cease to be required for emergency purposes).

Subsection (1) explains that this section applies to biologicals that have not been used before the exemption under section 32CB covering them ceased to have effect, other than because the biological has been included in the Register (subsection 32CB(5) refers).

Subsections (2) and (3) empower the Secretary to arrange for the disposal of the unused biological in accordance with the regulations. The regulations made for the purposes of subsection 32CG(2) may set out the methods by which the biologicals are to be stored, supplied, destroyed, exported or otherwise disposed of.

Subsection (4) prevents the regulations prescribing a method of destruction for unused biologicals that would enable any person, other than the owner of the biological, to benefit from the disposal.

Section 32CH – Criminal offences for breaching a condition of an exemption
This section establishes a tiered criminal offence regime (see pages 33 to 35) for breaching a condition imposed under section 32CC on an exemption for emergency purposes given under section 32CB. The section mirrors the equivalent existing offence set out at section 41MNB in the Act for breaching conditions on emergency exemptions for medical devices under section 41GS.

The offences and penalties provided under this section reflect the risks posed to public health through non-compliance with conditions, with higher penalties applying where harm or injury occurs or is likely as a result of non-compliance. As biologicals covered by an exemption will probably not have undergone an evaluation under the Act, it is likely that conditions imposed will be intended in part to mitigate potential safety risk. It is thus important to provide a deterrent to non-compliance with conditions.

Subsection (1) provides that a person commits an offence if they breach a condition of the exemption granted under section 32CB and the action or omission that caused the breach is likely to cause a serious risk to public health. Subsection (2) provides that strict liability applies to paragraph (1)(b), in relation to the exemption status of the biological to reflect that there is no need to prove intent in relation to whether an exemption has or has not been given.

The penalty for an offence against subsection (1) is 5 years imprisonment or 2,000 penalty units or both. The penalty level reflects that all fault elements are to be shown in relation to the act or omission which caused the breach of the condition and the resultant serious risk to public health.

Subsection (3) provides that a person commits an offence if they breach a condition of an exemption granted under section 32CB, even if the breach is not likely to cause a serious risk to public health. The penalty is 4 years imprisonment or 240 penalty units, or both.

Subsection (4) mirrors subsection (2) in providing that strict liability applies to paragraph (3)(b) in relation to the exemption status of the biological.

Subsections (5) and (6) provide that a person commits a strict liability offence with a penalty of 60 penalty units for breaching a condition of an exemption under section 32CB. This strict liability offence is intended to create a deterrent to non-compliance irrespective of the intent of the person breaching the condition.

In relation to the above offences, a person covered by an exemption ought to be aware of the exemption and any conditions as these would be notified to them under section 32CE.

Section 32CI – Civil penalty for breaching a condition of an exemption
This section provides a civil penalty where a person breaches a condition imposed on an exemption given under section 32CB. The maximum civil penalty for contravention of this section is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

This civil penalty provision and the maximum penalty level are consistent with existing section 41MNC of the Act dealing with breaches of conditions imposed on emergency exemptions in relation to medical devices under section 41GS.

Section 32CJ – Criminal offences and civil penalty for biologicals not conforming to standards etc.
This section empowers the Secretary, by written notice, to require that a person undertake specified corrective action where they supply biologicals exempt under section 32CB for emergency purposes, and the biologicals do not meet the standards applicable to the biologicals or the biologicals are unfit for their intended purpose.

This section also establishes a tiered criminal offence regime (see pages 33 to 35) and a civil penalty provision for failure to comply with a notice given by the Secretary. This is to ensure that public health is not risked through continued supply or failure to recover biologicals that do not meet appropriate standards or are not fit for their intended purpose.

Subsection (1) sets out that this section applies in circumstances where a person supplies a batch of biologicals that are exempted under section 32CB, and the Secretary is satisfied that the biologicals included in that batch do not meet the required standards for the biologicals (section 10 of the Act refers) or the biologicals are otherwise not fit to be used for their intended purpose.

Subsection (2) empowers the Secretary to give a written notice to the person referred to in subsection (1) to require them to take steps to recover the biologicals included in the affected batch. Any biologicals in the affected batch that cannot be recovered, such as those that have been used in the treatment of a person, are exempted from the requirement.

Subsection (3) sets out the types of actions that the notice given under subsection (2) may specify for the recovery of unused non-conforming biologicals. The notice may specify the steps to be taken to recover the biologicals, the manner in which the steps are to be taken and a reasonable period within which the steps are to be taken.

Subsection (4) provides that the Secretary must, as soon as practicable after giving the notice, cause particulars of it to be published in the Gazette.

Subsection (5) explains that a notice given under subsection (2) is not a legislative instrument as it is necessary to effect recovery of particular, specified, biologicals and is therefore not of a legislative character. A decision under this section is reviewable under section 60 of the Act.

Subsections (6) to (10) set out criminal offences for failure to comply with the any of the requirements specified in a notice given under subsection (2). These offences are consistent with and include the same penalties as existing subsections 30F(4B) to (6) in the Act relating to recovery of medicines or therapeutic devices covered by an emergency exemption under section 18A,

Subsection (6) provides that a person commits an offence if they fail to comply with a notice specifying a particular requirement, and as a result of the failure to comply harm or injury to any person has occurred or will occur from the use of the biologicals, or would occur if any of the biologicals covered by the notice were used. The maximum penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units, or both.

Subsection (7) provides that a person commits an offence if they fail to comply with a notice specifying a particular requirement, and as a result of the failure to comply the use of the biologicals would be likely to result in harm or injury to any person. The maximum penalty for an offence against this subsection is 2,000 penalty units. Subsection (8) provides that an offence against subsection 32CJ(7) is an offence of strict liability.

Subsections (9) and (10) provide that it is an offence of strict liability for a person to fail to comply with a particular requirement mentioned in a notice given under subsection 32CJ(2). The penalty for an offence against this subsection is 60 penalty units. This strict liability

offence is intended to create a deterrent to non-compliance with requirements irrespective of the intent of the person breaching the condition.

Subsection (11) provides a civil penalty for failure to comply with a notice given and applies a penalty of 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

Subdivision D – Exempting biologicals for special and experimental uses

This subdivision provides for exempting biologicals that are not included in the Register so they can be made available and used for special medical and experimental purposes.

Section 32CK – Approvals for importing, exporting or supplying a biological for special and experimental purposes

Subsection (1) empowers the Secretary to grant an approval, by notice in writing, for a person to import, export or supply a biological, specified in the notice, either for use in the medical treatment of another person or solely for experimental purposes in humans.
For example, clinical researchers may seek approval under this section to undertake the final stage of testing for a biological in humans to confirm the biological's safety, efficacy and other clinical characteristics to support an application for approval of the biological and inclusion of it in the Register (new sections 32DA and 32DD refer). An approval under this section may also be sought by a medical practitioner seeking to use a biological that has not received approval for a patient for whom no other treatment is available or appropriate.

Subsection (2) provides that the power of the Secretary to grant an approval does not apply if the biological is included in the Register, the person is exempt under subsection 32CA(1) in relation to the biological or if the biological is exempted under subsection 32CA(2). This is because the purpose of the exemption is to enable biologicals that are otherwise not included in the Register or exempted to be made available.

Subsections (3) and (4) set out the requirements for an application to seek approval to use a specified biological for the treatment of another person or solely for experimental purposes in humans, respectively.

Subsection (5) requires that the Secretary consider applications made under subsections (3) and (4) and notify the applicant as soon as practicable after making the decision to grant or refuse an exemption. Where the application is for the use of a biological solely for experimental purposes in humans, subsection 32CK(5) requires that the information submitted with the application must be evaluated. Where the Secretary refuses an application reasons for the decision must be given in the notice.

Subsections (6) to (9) provide for conditions to be placed on an approval given under this section. Subsection (6) empowers the Secretary to impose conditions on an approval given under subsection (1) and for those conditions to be set out in the approval notice. Subsection 32CK(7) provides that conditions imposed under subsection (6) may include, but are not limited to, conditions in relation to the payment of charges that may be made for the biological approved under subsection (1).

Subsection provides that regulations, made for the purposes of this subsection, may set out conditions to apply to approvals for the use of a biological solely for experimental purposes.

Such conditions would be additional to any imposed by the Secretary under subsection (6). For example, the regulations may make general conditions in relation to the use of biologicals for solely experimental purposes under an approval given under subsection (1), such as that all information regarding the safety or efficacy of the biological gained from the experimental purpose use be provided to the Secretary.

Subsection (9) provides that a person commits an offence with a penalty of 60 penalty units if the person breaches a condition of an approval under this section. This reflects the importance of conditions in supporting the safe use of biologicals for experimental and special clinical purposes that have not been assessed and included in the Register.

Subsection (10) is declaratory and explains that an approval under subsection (1) is not a legislative instrument as the decision to grant or refuse an approval is made on a case-by-case basis on expert information and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32CL – Conditions of use of biological for experimental purposes in humans
This section provides that conditions may be imposed on a person (known as the ***experimenter***) where they use a biological on humans for experimental purposes that has been approved, under subsection 32CK(1) in relation to another person for importation into or supply in Australia for solely experimental purposes.

Subsection (1) provides that regulations may be made specifying the conditions, if any, that the use of the biological for experimental purposes is to be subject to and the conditions can relate to any one or more of the matters set out in paragraphs (1)(c) to (f) relating to use of the biological.

For example, where a lead researcher is approved under subsection 32CK(1) to import or supply a biological solely for experimental purposes and an experimenter working with the lead researcher uses the biological in a clinical trial and administers it to trial participants, the experimenter would be subject to any conditions imposed under this section.

Subsection (2) provides that a person commits an offence with a penalty of 60 penalty units if they breach a condition imposed under the regulations made for the purposes of this section. This reflects the importance of conditions in supporting the safe use of biologicals for experimental purposes that have not been assessed and included in the Register.

Section 32CM – Exemptions for medical practitioners
Subsection (1) empowers the Secretary to authorise, in writing, specific medical practitioners to supply specified biologicals that are not included in the Register for the treatment of humans, to the class or classes of recipients specified in the authority granted by the Secretary. For example, a specialist medical practitioner may be authorised under this section to supply a biological that is not included in the Register to patients for whom no other alternative approved biological or other therapeutic good is available or suitable.

In authorising a medical practitioner to supply the specified biologicals, the Secretary may, under subsection (2), impose conditions and set these out in that authorisation.

Subsection (3) provides that the Secretary may impose conditions (or additional conditions) on an authority given to a person under subsection (1) by giving to the person written notice of the conditions (or additional conditions).

Subsection (4) provides that an authority under subsection (1) may only be given to a medical practitioner in a class of medical practitioners specified in regulations, or to a medical practitioner who has ethics committee approval to supply the biological. (Regulations may be made to set out exceptional circumstances where medical partitioners who do not have access to an ethics committee may supply biologicals.)

Subsections (5) and (6) provide that regulations may specify the class or classes of patients who may receive biologicals covered under and authorisation and the circumstances in which a biological may be supplied under an authority under subsection (1).

Subsection (7) explains for the benefit of readers that an authorisation under subsection (1) is not a legislative instrument as it applies to specific medical practitioners and hence is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Subsection (8) defines ***medical practitioner*** for the purposes of this section as a person who is registered, in a state or internal territory, as a medical practitioner.

Section 32CN – Criminal offences relating to the giving of an authority to a medical practitioner

This section establishes a tiered criminal offence regime (see pages 33 to 35) for medical practitioners authorised under subsection 32CM(1) who supply specified biologicals where the supply is not:

- in accordance with the authority,
- in accordance the conditions imposed in relation to the authority, or
- in accordance with the circumstances prescribed in the regulations made under subsection 32CM(6).

Subsection (1) provides that a medical practitioner commits an offence if they supply a biological not in accordance with the authority, conditions or regulations applying to it and as a result the use of the biological has or will, or if it were used it would, result in harm or injury to any person. The penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units or both. The note under this subsection explains that a person may, alternatively, be convicted of an offence against subsection 32CN(4) which provides a lesser penalty as there is no harm element involved under that subsection.

Subsection (2) provides that a medical practitioner commits an offence with a maximum penalty of 2,000 penalty units if they supply a biological not in accordance with the authority, conditions imposed on that authority or the circumstances prescribed in the regulations applying to it and as a result the use of the biological, if it were used, would likely result in harm or injury to any person. Subsection (3) provides that an offence against subsection (2) is an offence of strict liability.

Subsection (4) provides that a medical practitioner commits an offence if they supply a biological not in accordance with the authority, conditions imposed on that authority or the

circumstances prescribed in the regulations applying to it. The maximum penalty for an offence against this subsection is 500 penalty units.

The offences and penalties provided under this section reflect the risks to public health from non-compliance with requirements of authorisations given under section 32CM, particularly given the trusted role of medical practitioners in protecting and promoting public health.

Subdivision E – Exempting biologicals where substitutes are unavailable etc.

The purpose of this subdivision is to enable biologicals that are not included in the Register to be made available where they can substitute for biologicals that are included in the Register but the latter are unavailable or in short supply.

Section 32CO – Approvals where substitutes for biologicals are unavailable etc.
This section empowers the Secretary to grant, by notice in writing, approval to a person to import or import and supply in Australia specified biologicals where therapeutic goods included in the Register that could act as a substitute for the biological are in short supply or unavailable, or where no therapeutic goods that are included in the Register would be able to act as a substitute.

Subsection (1) provides for the circumstances when approval may be given by the Secretary when therapeutic goods that could substitute for the biological are in short supply or unavailable, while subsection (2) provides for approval to be given where no therapeutic goods in the Register could act as a substitute for the biological.

To provide an approval under subsection (1) for the importation or the importation and supply of a specified biological in Australia, the Secretary must be satisfied of the following:

- that other therapeutic goods that are included in the Register and that could be used in substitution for the biological, are unavailable or in short supply; and
- either the biological that is sought to be approved under this section is registered or otherwise approved for use in at least one foreign country that the Secretary specifies under subsection (5) *or* an application to include the biological in the Register in Australia has been made in accordance with the requirements under section 32DA or 32DD; and
- the biological sought to be imported or imported and supplied must be of a kind specified by the Secretary in a determination made under subsection (6); and
- that an approval under this section is necessary in the interests of public health.

To provide an approval under subsection (2) the Secretary must be satisfied of the following:

- that no other therapeutic goods that are included in the Register could act as a substitute for the biological; and
- an application to include the biological in the Register in Australia has been made in accordance with the requirements under section 32DA or 32DD; and
- the biological sought to be imported or imported and supplied must be of a kind specified by the Secretary in a determination made under subsection (6); and
- that an approval under this section is necessary in the interests of public health.

Where a biological that is not included in the Register is necessary for the treatment of individual patients, approval for the supply of these biologicals can be sought through sections 32CA, 32CK or 32CM, where appropriate.

Subsection (3) sets out the requirements for making an application for approval under this section, and subsection (4) requires that the Secretary must consider an application made and notify the applicant of the Secretary's decision as soon as practicable after the decision is made. Where the decision is not to grant the approval reasons must be given in the notice.

For the purposes of granting an approval, subsections (5) and (6) empower the Secretary to specify by legislative instrument foreign countries for the purposes of subparagraph (1)(d)(i) and the kinds of biologicals that can be the subject of an approval for the purposes of subsections (1) and (2).

The purpose of the determination at subsection (5) is to ensure that only those countries that apply suitably rigorous checks on therapeutic good safety and efficacy are recognised for the purpose of identifying suitable substitute biologicals. The purpose of the determination at subsection (6) is to ensure approvals under this section are not used inappropriately and correspond with identified shortages or unavailability of other approved therapeutic goods that are in the Register.

Subsection (7) provides that the Secretary may apply conditions to an approval under this section and these are to be specified in the approval notice given under subsection (3).

A person commits an offence with a maximum penalty of 60 penalty units under subsection (8) if they breach a condition imposed on an approval. This reflects the public health risk posed by non-compliance with conditions and provides a deterrent to non-compliance.

Subsections (9) to (12) set out how long an approval is valid for and when an approval is taken to have lapsed. An approval is valid until such time as specified in the approval notice and lapses when that time ends or if the biological is approved for inclusion in the Register (as an approval under this section would no longer be required to make the biological available). Where the approval lapses as a result of the time expiring subsection (12) provides that another approval may be granted to replace it.

Subsection (11) provides that an approval is also taken to lapse if a condition of the approval has been contravened or if any of the requirements that the Secretary must be satisfied of no longer exist: for example, if approved therapeutic goods in the Register that could act as a substitute become available. Where this occurs the Secretary must notify the person, who was granted the approval, to advise them that the approval has lapsed.

Subsection (13) explains that an approval is not a legislative instrument as the decision to grant or refuse an approval is made on a case-by-case basis on expert information and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Division 4 – Including biologicals in the Register

The purpose of this Division is to enable applications to be made and assessed for the inclusion of biologicals in the Register. This Division includes transitional provisions for biologicals currently included in the Register, or where applications have been made for inclusion in the Register, as medicines or therapeutic devices under Part 3-2, or as medical devices under Chapter 4, of the Act.

Subdivision A – Preliminary

Section 32D – What this Division is about
This section gives an overview of the Division. It identifies that the Division provides for the inclusion in the Register of biologicals either as Class 1 biologicals or as a class other than Class 1 (section 32AA provides for the regulations to prescribe different classes). This section does not limit the classes of biologicals to two classes only.

Subdivision B – Class 1 biologicals

32DA – Application for inclusion in the Register
This section provides for applications to be made for including a Class 1 biological (section 32AA refers) in the Register.

Subsection (1) explains that an application is required to seek inclusion of a biological in the Register and subsection (2) sets out the requirements for an effective application including that it is made on a form approved in writing by the Secretary (subsection (4) refers).

Subsection (3) sets out the matters that an applicant must certify regarding the biological and relates to the safety of the biological, including that it conforms with all applicable standards (section 10 of the Act refers), and other matters. Subsection (4) explains that the approved application form to be used under subsection (2) may require or permit the application to be submitted in electronic format. For example, an on-line application form may be approved to be used, as is currently approved for applications for listed goods under sections 26 and 26A of the Act.

Section 32DB – Inclusion of Class 1 biologicals in the Register
Subsections 32DB(1) and (2) provide for inclusion of a Class 1 biological in the Register by the Secretary if an application is made in accordance with the requirements under section 32DA and for the Secretary to assign a unique biological number (item 2 refers) to be assigned to the biological.

The biological number can include any combination of numbers, letters or symbols (new subsection 32BJ(2) refers). The number assigned assists in identifying the biological in the Register and can be required (new subsection 32BF(6) refers) to be included on the label to identify the biological including for recall or recovery purposes.

As soon as practicable following inclusion of the biological in the Register subsections (3) and (4) require that the Secretary give the applicant a certificate of the inclusion of the biological in the Register specifying the biological number and the day on which the biological's inclusion in the Register is taken to commence.

Subsection (5) provides that a biological remains in the Register in relation to the person until the entry is cancelled by the Secretary under Part 3-2A. New Division 7 under this Part provides that cancellation may be either on the Secretary's own initiative in specified circumstances or in response to a request from the person in relation to whom the biological is included. The note under subsection (5) explains that a biological is considered to be not included in the Register (except for certain conditions relating to obligations to provide information, recall of batches, etc) while it is suspended under Division 6.

Section 32DC – Refusal to include Class 1 biological in the Register
This section requires that the Secretary provide notification with reasons to an applicant if she or he refuses an application made under section 32DA and that this is to be provided to the applicant as soon as practicable after the decision to refuse the application is made.

Subdivision C – Biologicals other than Class 1 biologicals

This subdivision provides for applications to be made and for inclusion in the Register of biologicals in a class or classes other than Class 1. New section 32AA provides for regulations to prescribe different classes of biologicals and it is expected that the regulations will specify four classes of biologicals ranging from lower risk to higher risk. Therefore, it is anticipated that this Subdivision will apply to Classes 2 to 4, or any other classes that are later specified in the regulations.

Section 32DD – Application for inclusion in the Register
This section provides for applications to be made for including a biological other than a Class 1 biological (section 32AA refers) in the Register.

Subsection (1) explains that an application is required to seek inclusion of a biological in the Register and subsection (2) sets out the requirements for an effective application including that it is made on a form approved in writing by the Secretary (subsection (4) refers). The note under this subsection explains that, in addition to the application fee, a fee is payable for the evaluation of the details in the application (sections 32DI to 32DM refer).

Subsection (3) empowers the Secretary to approve different forms for different classes of biologicals where the regulations made under section 32AA prescribe different classes. For example, a more detailed application form may be approved for applications seeking to include a biological that is a Class 4 biological (a higher risk biological) in the Register than that approved for the inclusion of a Class 2 biological (a slightly lower risk biological. Section 32DA provides for the making of applications and requirements that must be satisfied in an application for the inclusion of a Class 1 biological in the Register as such biologicals will have a lower risk profile.

Subsection (4) explains that the approved application form to be used under subsection (2) may require or permit the application to be submitted in electronic format. For example, an on-line application form may be approved to be used, as is currently approved for applications for listed goods under sections 26 and 26A of the Act.

Section 32DE – Evaluation of biologicals
This section provides for the evaluation of applications and information submitted with applications, such as clinical trial data, provided under section 32DD above.

Subsection (1) sets out the matters the Secretary, or a delegate of the Secretary such as a medical evaluator at the TGA, must have regard to when evaluating an application made under section 32DD. These matters relate to quality, safety, efficacy, appropriate manufacturing arrangements, compliance with relevant standards, non-inclusion of prohibited substances, presentation of the biological, compliance with advertising requirements, and any other matters if any that the Secretary considers relevant.

Subsection (2) provides for recognition of manufacturing standards and approvals given by certain overseas authorities where a biological seeking inclusion in the Register is manufactured, or a step in the manufacture, occurs outside of Australia. This subsection refers across to the relevant provisions set out under section 25 of the Act in relation to evaluation, for inclusion in the Register as registered goods, of medicines and therapeutic devices where overseas manufacture is involved.

The subsection provides that the evaluation of manufacturing and quality control procedures for biologicals, where a manufacturing step occurs outside of Australia, is the same as that applied to other therapeutic goods such as registered medicines and therapeutic devices.

Section 32DF – Inclusion of biological in the Register
This section provides for the inclusion in the Register of biologicals, other than Class 1 biologicals (section 32DB refers).

Subsection (1) provides for the inclusion of a biological in the Register in relation to the applicant (other than Class 1 biologicals) by the Secretary where certain requirements are met. Under this subsection, the Secretary must include the biological in the Register if an application has been made in accordance with the requirements under section 32DD, no part of the evaluation fee that is due and payable remains unpaid, and after evaluating the application under section 32DE, the Secretary decides that it is appropriate to include the biological in the Register.

Subsection (2) requires that where a biological is included in the Register it is to be assigned a unique biological number (item 2 refers). The biological number can include any combination of numbers, letters or symbols (new subsection 32BJ(2) refers). The number assigned assists in identifying the biological in the Register and can be required (new subsection 32BF(6) refers) to be included on the label to identifying the biological in the marketplace including for recall purposes.

As soon as practicable following inclusion of the biological in the Register subsections (3) and (4) require that the Secretary give the applicant a certificate of inclusion of the biological in the Register specifying the biological number and the day on which the biological's inclusion in the Register is taken to commence.

Subsection (5) provides that a biological remains in the Register until the biological's entry in the Register is cancelled by the Secretary. New Division 7 under this Part provides that cancellation may be either on the Secretary's own initiative in specified circumstances or in response to a request from the person in relation to whom the biological is included. The note

under subsection (5) explains that a biological is considered to be not included in the Register (except for certain conditions relating to obligations to provide information, recall of batches, etc) while it is suspended under Division 6.

Section 32DG – Refusal to include biological in the Register
This section requires that the Secretary provide notification with reasons to an applicant if she or he refuses an application made under section 32DD and that this is to be provided to the applicant as soon as practicable after the decision to refuse the application is made.

Section 32DH – Lapsing of application
This section provides the circumstances where an application made under section 32DD is taken to have lapsed and, therefore, the application is no longer able to be considered for inclusion of the biological in the Register under that application. Another application may be made in respect of the biological where the previous application lapses and the requirements set out at section 32DD apply to that new application.

Subsection (1) provides that an application for a biological made under section 32DD lapses if the applicant:

- fails to pay the applicable evaluation fee in full at the end of the period of 42 days after the day on which the part become due and payable; or
- if they or someone acting for them gives false or misleading information (including information given for the purpose of a requirement under section 32JA); or
- if they fail to give information relating to patient data (such as data gathered during clinical trials) for the biological where the Secretary gives a notice under section 32JA requiring it.

Subsection (2) defines ***patient data*** in relation to a biological for the purposes of this section where the Secretary requests such information under section 32JA. This information pertains to information gathered from clinical trial use of the biological and therefore provides necessary information to assist the Secretary, or delegate, in undertaking a full evaluation of the safety, etc of the biological.

Section 32DI – Evaluation fee
This section provides that the Secretary must notify in writing an applicant who submits an application under section 32DD of the amount of the evaluation fee, specified in, or determined in accordance with the regulations, that is payable by the applicant in respect of an evaluation of the biological, under section 32DE. The regulations may either specify an amount or set out a calculation to determine the amount, such as an amount per page of data submitted with the application.

The evaluation fee may vary depending on, for example, the type of evaluation required, the class of the biological, or the matters that need to be evaluated in relation to the biological.

Section 32DJ explains when the payment notified by the Secretary is to be paid.

Section 32DJ – When evaluation fee due for payment
Subsection (1) provides that the evaluation fee prescribed under section 32DI is due and payable on the day notified, subject to section 32DK which provides for payment by instalment and section 32DM which provides for a reduction in the fee where the evaluation is not completed on time.

Subsection (2) provides that the fee is to be paid in the manner prescribed by the regulations.

Section 32DK – Payment if evaluation fee by instalments
This section enables the regulations to provide for the payment of an evaluation fee by instalments, and the fee becomes due and payable at such times as are to be ascertained in accordance with the regulations.

The regulations may provide under subsection (2) that evaluation fees cannot be paid by instalment if any part of an instalment of that, or any other, evaluation fee payable by the person was unpaid immediately after the time when it became due for payment. Subsection (4) explains subsection (2) does not limit subsection (1).

Subsection (3) provides that if the regulations disallow the payment of an evaluation fee by instalment if other fees remain unpaid then if any instalment of an evaluation fee payable under section 32DI is not paid on time then the remaining balance of the evaluation fee becomes due and payable immediately. This is to prevent misuse of the provisions for payment by instalment and to ensure that the cost of undertaking evaluations is recovered.

Section 32DL – Recovery of evaluation fee
This section provides that evaluation fees may be recovered as a debt due to the Commonwealth.

Section 32DM – Reduction of evaluation fee where evaluation not completed within prescribed period
Subsection (1) provides that an applicant is not required, under sections 32DI, 32DJ or 32DK, to pay more than ¾ of the applicable evaluation fee before the evaluation of their application is completed if a maximum evaluation period is specified in the regulations (item 60 refers).

Subsection (2) requires that the Secretary notify the applicant in writing of the day the evaluation is completed. This is necessary to determine if the evaluation is completed within the period, if set, under the regulations

Where the evaluation is not completed in the set time, subsection (3) explains that the full evaluation fee payable is then ¾ of what it would have been had the evaluation been completed in the time prescribed.

Subsection (4) provides that where an evaluation is completed in the set time and any part of the evaluation fee is unpaid (for example, if ¼ of the fee was withheld until the evaluation was completed, consistent with subsection (1)), then the outstanding amount is due and payable on the completion of the evaluation.

Subsection (5) provides that the evaluation is taken to be completed, for the purposes of this section, immediately before the first copy of evaluation report or summary of the report, if given, is given to either or both the applicant or an advisory committee for biological applications. Where a report or summary is given then the date it is given will be the day specified in the notice. However, if no report or summary is given, then the evaluation is completed on the day specified in the notice sent to the applicant in subsection (2). For example, more straight-forward applications may not require evaluation reports or summaries to be given to an advisory committee or the applicant.

The note under this subsection explains that this provision is to ensure that if an applicant becomes aware through either of these events that the likely decision of the Secretary will be to refuse to include the biological, that is the subject of the application, in the Register, that the person cannot withdraw their application to avoid payment of any part of the evaluation fee that may be outstanding. This is because the work involved in undertaking the evaluation has been completed and the cost for undertaking this work needs to be recovered.

Subsection (6) explains that a notice given under subsection (2) is not a legislative instrument as it relates to a specific evaluation of an application for the inclusion of a biological in the Register and administratively applies the legislation, therefore, it is not legislative in character.

Section 32DN – Transitional provisions for existing biologicals

This section sets out transitional provisions for biologicals that are currently in the Register as a registered or listed good or as a medical device; or where an application is made for such an inclusion in the Register prior to the commencement of this Part.

Subsection (1) applies to biologicals that, before the commencement of this section, were included in the Part of the Register for registered goods or listed goods (under Part 3-2) or for medical devices (under Chapter 4). This subsection requires the Secretary, as soon as practicable, after the commencement of this section to cancel the inclusion of such a biological in that particular part of the Register and include it in the Register under Part 3-2A in relation to the person. As a result of that cancellation and inclusion (movement) in the Register of the biological, the Secretary must also, as soon as practicable after the commencement this section, vary the Register. The decision must be in writing.

Subsection (2) provides that where an application is made to include a biological in the Register as a registered or listed good (under Part 3-2) or as kind of medical device (under Chapter 4), prior to the commencement of this Part, and the application hasn't been finally determined or withdrawn before this Part commences, then the application continues to be dealt with under Part 3-2 or Chapter 4 of the Act, as relevant, until it is finally determined.

If the application is successful, the biological is included in the relevant part of the Register according to the Part applied for and considered under. That is, if it was an application to include the biological in that part of the Register for registered goods then the application continues to be assessed according to Part 3-2 of the Act and if successful is included in the Register as a registered good.

Where the biological is included in the relevant part of the Register, then as soon as practicable, the Secretary must cancel the inclusion of the biological in that part of the Register, include the biological in the Register under Part 3-2A of the Act (that is, move the entry in the Register), and vary the Register as a result of that cancellation and inclusion. The decision must be in writing. For the purposes of subsection (2), subsection (3) defines ***finally determined*** and provides for any reviews of the decision to be completed and exhausted.

Subsections (4) to (7) provide that where a biological is moved in the Register to that part for biologicals the Secretary must notify the person, in relation to whom it is included, to advise them of the move, assign a unique biological number to the biological and give a certificate of the inclusion of the biological to the person, as soon as practicable after the biological is

included in the Register under Part 3-1. Subsection (7) provides that the certificate must specify the biological number and the day the inclusion of the biological in the Register under Part 3-2A commences.

Subsection (8) explains that a biological remains in the Register until the entry is cancelled by the Secretary. The note under subsection (8) explains that while a biological is suspended it is taken not to be in the Register (except for certain conditions relating to obligations to provide information, recall of batches, etc). This is consistent with the duration of entry specified for new applications for inclusion in the Register as a Class 1 or other class of biological under subsections 32DB(5) and 32DF(5).

Subsection (9) provides that where a biological is moved in the Register under subsections (1) or (2), an annual charge is not payable for the biological in the financial year it is moved. This is because an annual charge will have been payable in respect of the biological's inclusion in the Register either as a registered or listed good (under Part 3-2) or as an included kind of medical device (under Chapter 4) prior to it being moved to the part of the Register for biologicals (under Part 3-2A). This subsection prevents double-payment of the charge for the one entry of a therapeutic good in the Register.

Subsection (10) explains that a decision under this section is not an initial decision for the purposes of section 60. This is because this section merely moves a biological already included in the Register and does not provide for decisions to be made regarding inclusion in the Register. The decisions to include or not include therapeutic goods, identified under this Part as biologicals, in the Register were taken under Part 3-2 (for registered and listed goods) and chapter 4 (for medical devices) and, therefore, when those decisions were made they were subject to reviews under section 60 of the Act.

Section 32DO – Criminal offences for false statements in applications for including biologicals in the Register

This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person makes a false or misleading statement in connection with an application for inclusion of a biological in the Register.

Subsection (1) provides that a person making such a statement commits an offence if the use of the biological has or will result in harm or injury to any person, or it would result in harm or injury to any person if the biological were used. The penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units or both. The note under this subsection explains that a person may, alternatively, be convicted of an offence against subsection (4) which provides a lesser penalty as there is no harm element involved.

Subsection (2) provides that a person making such a statement commits an offence if the biological, if it were used, would be likely to result in harm or injury to any person. The penalty for an offence against this subsection is 2,000 penalty units. Subsection (3) provides that this is an offence of strict liability.

Subsection (4) provides that a person making such a statement commits an offence, regardless of whether the biological involved has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Section 32DP – Civil penalty for false statements in applications for including biologicals in the Register

This section sets out that a civil penalty applies for making a false or misleading statement in an application for inclusion of a biological in the Register. The maximum penalty for an offence against this section is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate. Section 32DP is based upon, and is consistent with (including in relation to maximum penalty), existing section 22B of the Act.

Section 32DQ – Criminal offence and civil penalty for failing to notify adverse effects etc. of biological while it is included in the Register

Subsection (1) provides that a person, in relation to whom the biological is included in the Register, commits an offence if they know that particular information is information of a kind listed in subsection (3) and they fail to give that information to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

Subsection (3) details the kinds of information that must be given, being information that:

- contradicts information already given by the person under the Act in relation to the biological including information about the safety, quality or efficacy of the biological;
- indicates that the use of the biological, in accordance with the recommendations for its use, may have an unintended harmful effect;
- indicates that the use of the biological, in accordance with the recommendations for its use, may not be as effective as suggested by either the application for inclusion of the biological in the Register or the information already given by the person under the Act.

The penalty for an offence against subsection (1) is 12 months imprisonment or 1,000 penalty units, or both.

Subsection (1) is based upon (including in relation to maximum penalty) existing subsection 29A(1) of the Act.

Subsection (2) is a civil penalty provision and provides that a person contravenes this subsection if:

- a biological is included in the Register in relation to the person, and
- they know that particular information is information of the kind listed in subsection (3), and
- they fail to give that information to the Secretary within the period specified in the Regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

The maximum civil penalty for contravention of subsection (2) is 3,000 penalty units for an individual or 30,000 penalty units for a body corporate. Subsection (2) is based upon and includes the same maximum penalty as existing section 29AA of the Act.

Section 32DR – Criminal offences and civil penalties for failing to notify adverse effects etc. of biologicals where application withdrawn or lapses

Subsection (1) provides that the Secretary may seek information, by notice in writing, from an applicant within 14 days of the applicant withdrawing their application or the application lapsing (section 32DH refers). The notice given under subsection (1) requires the applicant

to inform the Secretary in writing about whether they are aware of any information of a kind to which subsection (2) applies, and if they are aware of the existence of that information, to give it to the Secretary in writing.

Subsection (2) sets out the kinds of information the Secretary may ask for in a notice and is consistent with the information that may be sought under section 32DQ, above, in relation to biologicals included in the Register.

This information is necessary to ensure that if any person applies to include the biological in the Register, or to seek an exemption, approval or authorisation under this Act to import, export, manufacture, supply or use the biological that is the subject of the withdrawn or lapsed application, a decision in regard to such an application can be informed by all relevant information.

Subsection 32DR(3) provides that a person commits an offence if the Secretary gives a notice to the person under subsection (1) and they fail to comply with the notice within 30 days after the notice is given. The maximum penalty for a breach of this subsection is 12 months imprisonment or 1,000 penalty units or both, consistent with existing subsection 29B(3) of the Act.

Subsection (4) provides that a person commits an offence if the person gives information in purported compliance with a notice under this section and the information is false or misleading in a material particular. The maximum penalty for the offence under this subsection is 12 months imprisonment or 1,000 penalty units, or both, consistent with existing subsection 29B(4) of the Act.

Subsections (5) and (6) provide civil penalties for the same acts or omissions to act as those set out under subsections (3) and (4). The maximum civil penalties for contravention of either of these subsections is 3,000 penalty units for an individual or 30,000 penalty units for a body corporate.

The penalties under this section reflect the importance of applicants providing information to the Secretary about the quality, safety and efficacy of biologicals and provide a deterrent for non-compliance with the requirements of a notice.

Subdivision F – Advice from Gene Technology Regulator

Section 32DS – Consultation with Gene Technology Regulator

This section provides that the Secretary is to advise the Gene Technology Regulator and seek advice if an application is received for the inclusion of a biological in the Register where the biological is or contains a genetically modified product or genetically modified organism.

The Gene Technology Regulator may then give advice but this must be given within the period specified in the notice given by the Secretary. This is to ensure timely consideration of the application.

Subsection (5) provides that if advice is in force under section 32DT in relation to a class of biologicals the Secretary does not need to seek advice from the Regulator if the application is for a biological in that class.

Subsection (6) explains that a notice given under subsection (2) is not a legislative instrument as it is given in relation to a specific biological application in applying the legislation and, therefore, is not legislative in character.

Section 32DT – Secretary may seek advice about classes of GM products of genetically modified organisms

This section provides that the Secretary may request advice from the Gene Technology Regulator regarding biologicals that are or contain genetically modified (GM) products or genetically modified organisms belonging to a class or classes of GM products or genetically modified organisms. Subsection (3) provides that the Gene Technology Regulator may, in response to the request, provide written advice in response to the request and the matters specified in it which the Secretary seeks advice on.

Subsection (4) provides that if advice is given it remains in force until the Gene Technology Regulator advises in writing to the Secretary that it has been withdrawn.

Section 32DU – Secretary to take advice into account

This section provides that if the Gene Technology Regulator gives advice under section 32DS or 32DT, above, the Secretary must ensure that advice is taken into account in making a decision on an application to which the advice relates.

Division 5 – Conditions

This Division provides for kinds of conditions to be applied to biologicals included in the Register under Part 3-2A of the Act.

Some conditions apply automatically (refer to section 32EA) and other conditions can be set out in a legislative instrument made by the Minister (under section 32EC). Additional conditions can be imposed at the time of inclusion of the biologicals or after the biologicals have been included in the Register (refer to sections 32ED and 32EE). The conditions imposed under section 32ED can be varied or removed on the request of a person or on the Secretary's own initiative.

Criminal offence and civil penalty provisions apply (refer to sections 32EF and 32EG) for breaching a condition imposed.

Section 32E – What this Division is about

This section provides an overview of what this Division is about.

Section 32EA – Conditions applying automatically

This section sets out the conditions that apply automatically to all biologicals that are included in the Register under this Part and relates to entry and inspection of premises that relate to the biological, provision of samples of biologicals, manufacturing, prevention of supply after the expiry date and advertising.

Subsection (1) provides power for an authorised person under the Act to enter and inspect premises at which the biologicals that are included in the Register are dealt with, such as a warehouse for storage. The conditions set out under subsection (1) also apply to premises outside Australia. Although the TGA has no jurisdiction in relation to overseas premises, it is for the sponsor to ensure that the authorised persons are able to enter those premises and for

those authorised persons to carry out their powers and functions set out under paragraphs (a) to (b). The conditions apply to the sponsor of the particular biological and any breach of condition may lead to the immediate cancellation of the inclusion of the biological in the Register (refer to paragraph 32GA(1)(h)), prosecution, or the imposition of a civil penalty by the court.

The authorised person may also undertake other activities while on the premises related to ensuring compliance with the requirements under the Act including taking still or moving images or recordings, eg: photos or video recordings; testing or taking samples of any biological, including any biologicals found that may not be included in the Register or not included in relation to that person. The authorised person can also request the production of certain documents relating to the biological. This is necessary to prevent counterfeiting or production of biologicals that are not included in the Register as such biologicals pose a risk to public health.

Subsection (2) provides that an authorised person must show their photo identity card (section 52 of the Act refers) to the occupier of the premises if requested to do so. An authorised person is not authorised to enter the premises mentioned in subsection (1) if the occupier of the premises asked the authorised person to show their photo identity card to him or her, and the authorised person refuses to do so.

The entry and inspection power is necessary to check compliance with the requirements of the Act and regulations and to determine whether any breaches have been committed which might seriously endanger public health. A similar power already exists in subsection 28(5) of the Act in relation to listed and registered goods.

Subsection (3) provides that it is a condition of inclusion in the Register that if requested by the Secretary a person in respect of whom a biological is included in the Register must deliver a reasonable number of samples of the biological within a period of not less than 14 days after the request is made and in accordance with any other requirements specified in the request.

Subsection (4) provides that it is a condition of inclusion in the Register that sponsors of biologicals advise the Secretary in writing if the manufacturer or manufacturing premises are to change from that advised in the application form, before this change occurs. Subsection (5) provides that for biologicals, other than Class 1 biologicals, each step in the manufacture is carried out by a manufacturer who, if in Australia, holds a licence under Part 3-3 (unless exempted from that Part, subsection (6) refers), or if overseas, by a manufacturer certified under subsection 32EB(2). This subsection does not apply to Class 1 biologicals as they are exempted from the operation and requirements of Part 3-3 of the Act due to their lower risk profile and minimal manufacture.

Subsection (7) provides than a certification under subsection 32EB(2) is not required to the extent to a step in relation to particular premises that was the subject of a recognised overseas evaluation (section 32DE refers). However, subsection (7) ceases to apply if either or both of the following occur: (a) that manufacturing step begins to be carried out at premises that are different to the premises in respect of which that evaluation was conducted; (b) that step begins to be carried out by a manufacturer that is different from the manufacturer in respect of which that evaluation was conducted.

Subsection (8) requires that the person in relation to whom the biological is included in the Register will not supply in Australia, or export, a batch of biologicals after the expiry date for the biologicals.

Subsection (9) requires that the person in relation to whom the biological is included in the Register will not advertise the biological for an indication other than that which has been accepted in relation to the biological for inclusion in the Register. This is to prevent inappropriate advertising of biologicals as this poses a risk to public health as biologicals may then be used for purposes they have not been shown to be safe or effective for.

Section 32EB – Certification of manufacturing steps outside Australia

This section provides that where a step in the manufacture of a biological (including multiple steps or the complete manufacture) occurs overseas, the person in relation to whom the biological is included in the Register may apply to the Secretary seeking certification that the step in the manufacture of the biological that is to be carried out outside Australia and the quality control procedures used are acceptable. The Secretary is empowered to grant or refuse to grant such a certification. The Secretary must give the person a written notice of the certification.

Subsection (3) provides that, in giving a certification, the Secretary may take into account a recognised overseas attestation of conformity or other acceptable form of evidence from a relevant overseas authority which establishes that the manufacture of the goods is of an acceptable standard.

This is similar to the considerations to be made by the Secretary under subsections 25(2), (2E), (2F) and (2G) in relation to registered goods and corresponds to the way in which they apply for the purposes of paragraph 25(1)(g). That is, the application of recognition for overseas manufacturing certification for biologicals is consistent with the provisions for overseas certification for registered goods under Part 3-2 of the Act. However, the TGA can still require the audit and review of those overseas premises.

Overseas manufacturing approval either through recognised attestation of conformity and approval and/or certification under this section is a condition of inclusion of a biological in the Register (paragraph 32EA(5)(b) refers).

Section 32EC – Imposition of conditions by legislative instrument

This section empowers the Minister, by legislative instrument, to determine conditions that are to apply to the inclusion of a biological in the Register. These conditions are additional to those applying automatically under section 32EA.

Subsection (2) sets out the matters to which the legislative instrument may set conditions in regard to. Subsection (3) explains that different conditions may be imposed for 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). Very specific conditions applying on particular biologicals in particular circumstances may be imposed under section 32ED.

Section 32ED – Imposition of conditions at time biological included in the Register
This section empowers the Secretary, by notice in writing given to the person in respect of whom the biological is to be included in the Register, to impose specific conditions on biologicals at the time they are included in the Register. These are in addition to any conditions imposed automatically under section 32EA or conditions set out in a legislative instrument made by the Minister under section 32EC.

Section 32EE, below, provides for the Secretary to impose new conditions, or vary or remove conditions that have been imposed under this section after the biological is included in the Register.

Subsection (2) explains that a notice given by the Secretary is not a legislative instrument. This is because the notice is an administrative application of this section applying only to the biological specified in the notice and is therefore not legislative in character.

Section 32EE – Imposition or variation or removal of conditions after biological included in the Register
Subsection (1) empowers the Secretary, by notice given in writing to the person in respect of whom the biological is included in the Register, to impose new conditions or vary or remove existing conditions that have been applied by the Secretary under section 32ED or this subsection.

Subsection (2) explains that the above power can be exercised on the Secretary's own initiative or following a request by the person concerned. Where a person applies to request a change to the conditions imposed by the Secretary this must be accompanied by the relevant fee to enable the request to be dealt with.

Subsection (3) sets out when the imposition, variation or removal of a condition is to take effect. If the condition change has been necessary to prevent imminent risk of death, serious illness or serious injury the change takes effect on the day the person is given the notice of the change. In other circumstances the change takes effect on a day specified in the notice but not sooner than 28 days after the person is given the notice.

Subsection (4) is declaratory and explains that a notice given by the Secretary is not a legislative instrument. This is because the notice is an administrative application of this section applying only to the biological specified in the notice and is therefore not legislative in character.

32EF – Criminal offences for breach of condition
This section establishes a tiered criminal offence regime (see pages 33 to 35) where a person, in respect of whom a biological is included in the Register, breaches a condition of that inclusion as imposed under section 32EA, 32EC, 32ED or 32EE.

Subsection (1) provides that a person, in respect of whom a biological is included in the Register, commits an offence if they breach a condition and the act or omission that caused the breach results in or will result in harm or injury to any person. The penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units or both. The note under this subsection explains that a person may, alternatively, be convicted of an offence against subsection (4) which provides a lesser penalty as there is no harm element involved.

Subsection (2) provides that a person, in respect of whom a biological is included in the Register, commits an offence if they breach a condition and the act or omission that caused the breach is likely to result in harm or injury to any person. The penalty for an offence against this subsection is 2,000 penalty units. Subsection (3) provides that an offence against this subsection is an offence of strict liability.

Subsection (4) provides that a person, in respect of whom a biological is included in the Register, commits an offence if they breach a condition regardless of whether the breach has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Section 32EG – Civil penalty for breach of condition
This section provides a civil penalty where a person, in respect of whom a biological is included in the Register, breaches a condition imposed on the inclusion of the biological in the Register. The maximum civil penalty is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

Division 6 – Suspension from the Register

Section 32F – What this Division is about
This section provides an overview of what this Division is about.

Section 32FA – Suspension of biological from the Register
This section empowers the Secretary to suspend a biological from inclusion in the Register in certain prescribed circumstances.

Under subsection (1) the Secretary may suspend biologicals (paragraph (1)(a)) if she or he is satisfied that there is a serious health risk to consumers of the biologicals through continued availability of the biologicals and where it is likely that the reason(s) for the suspension will be able to be addressed and corrected during the period of the suspension.

The Secretary may also suspend the biologicals (paragraph (1)(b)) if she or he is satisfied that there are grounds for cancelling the inclusion under new Division 7, other than because of an imminent risk of death, serious illness or serious injury if the biological continued to be included in the Register. In such circumstances suspension would not be appropriate and instead the Secretary may cancel the biological's inclusion in the Register under section 32GA.

The decision to suspend the inclusion of the biological in the Register under subsection (1) must be given by written notice to the person in relation to whom the biological is included.

Subsection (2) requires that before suspending a biological from inclusion in the Register because it is likely that there are grounds for cancelling the entry of the biological from the Register under section 32GC, the Secretary must advise the person in relation to whom the biological is included, of the proposed suspension in writing and set out the reasons for the suspension. The Secretary must also give the person reasonable opportunity, not less than 28 days after the notice is given, to make submissions in relation to the proposed suspension.

Subsection (3) requires that the Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions given by that person in response to the written notice given under paragraph (2)(b).

Subsection (4) provides that the maximum period of suspension is to be 6 months and that the period of suspension must be included in the notice given under subsection (1).

Under subsection (5) the Secretary must cause a notice of decision to suspend biologicals from inclusion in the Register to be published in the *Gazette* as soon as practicable after notification has been given to the person in relation to whom the biological is included. The notice should set out the particulars of the suspension.

Subsection (6) explains that a notice given under subsection (1) is not a legislative instrument. This is because it relates to a specific biological and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is an initial decision and is, therefore, reviewable under section 60 of the Act.

Section 32FB – When suspension takes effect etc.
This section specifies when a suspension under section 32FA takes effect and provides for the extension of a suspension.

Subsection (1) provides that where the suspension under section 32FA is due to the risk of potential death or serious illness or injury it is take effect from the day the notice is given to the person. In any other case, the suspension takes effect on the day specified in the notice, that day not being earlier than 28 days after the notice is given to the person in relation to whom the biological is included in the Register.

Subsection (2) provides that a suspension ceases when it is revoked section 32FC, the original period specified under section 32FA ends, or an extension made under subsection (3) ends.

Subsection (3) allows the Secretary, by written notice to the person in relation to whom the biological is included in the Register, to extend the period of the extension for up to 6 months.

Subsection (4) provides that as soon as practicable after the Secretary gives notification of the extension under subsection (3), the Secretary must cause a notice to be published in the *Gazette* setting out particulars of the extension.

Subsection (5) explains that a notice given under subsection (3) to extend the period of suspension is not a legislative instrument. This is because it relates to a specific biological and administratively applies the legislation and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32FC – Revocation of suspension
This section deals with revoking a suspension under section 32FA.

Subsection (1) provides that the Secretary must revoke the suspension by written notice to the person in relation to whom the biological is included in the Register if the Secretary is satisfied that the grounds on which the inclusion in the Register was suspended no longer

applies and there are no other grounds for suspending the inclusion in the Register of the biological.

Subsection (2) provides that the revocation of the suspension can be made by the Secretary on her or his own initiative or following an application from the person in relation to whom the biological is included in the Register.

Subsection (3), requires that a notice be published in the *Gazette* setting out the particulars of the revocation of the suspension, as soon as practicable after notice is given under subsection (1) to the person in relation to whom the biological is included in the Register.

Subsection (4) also requires a written notification to be provided to the person in relation to whom biological is included in the Register where they make application for revocation of the suspension under paragraph (2)(a), and the Secretary decides not to revoke the suspension. The notification must include reasons for the decision.

Subsection (5) explains that a notice revoking a suspension under subsection (1) is not a legislative instrument. This is because it relates to a specific biological and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32FD – Effect of suspension
This section explains the effect of suspension under section 32FA.

Where the inclusion of a biological in the Register is suspended under section 32FA, the biological is taken, for the purposes of the Act, not to be included in the Register while the suspension is in operation, except in relation to certain provisions set out in subsection (1) that continue to apply.

Subsection (1) specifies the provisions that continue to apply as if the biological were not suspended from the Register. These are:

- section 32DQ – which sets out the criminal offences and civil penalties for failing to notify of adverse effects etc. of a biological that is included in the Register;
- Division 5 – which sets out the conditions applying automatically to a biological included in the Register, conditions applying on inclusion of the biological, additional conditions imposed by the Secretary, conditions applicable as set out in a legislative instrument made by the Minister;
- Section 32FB – which prescribes when a suspension takes effect including when a suspension ceases to have effect;
- Section 32FC – which provides for the revocation of a suspension;
- Division 7 – which provides that the Secretary may cancel the inclusion of a biological from the Register including while a suspension is in place (where the criteria for cancellation under this Division are met); and
- Division 9 – which provides that information or documents may be required to be given in relation to a biological that is included in the Register including while a suspension is in place.

The note under this subsection explains that a criminal offence or civil penalties may apply if a person deals in a biological that is not included in the Register, including while suspended from the Register.

Subsection (2) provides that the Secretary's power to cancel a biological from inclusion in the Register is not affected while the biological is suspended. Therefore, if a biological is suspended and there are grounds for cancellation the Secretary may cancel the biological from inclusion in the Register.

Division 7 – Cancellation from the Register

Section 32G – What this Division is about
This section provides an overview of what this Division is about.

Section 32GA – Immediate cancellation of biological from the Register in various circumstances
This section empowers the Secretary to immediately cancel a biological from inclusion in the Register in certain prescribed circumstances.

Subsection (1) sets out the circumstances in which the Secretary may cancel a biological from inclusion in the Register. The circumstances are:

- where there is an imminent risk of death, serious illness or serious injury if the biological remains in the Register;
- where the biological ceases to be a biological or a therapeutic good:
- an exemption is in force under section 32CA;
- the person in respect of whom the biological is included in the Register requests in writing that the entry be cancelled;
- the biological contains a substance that is prohibited from importation:
- the Secretary is satisfied that a statement that was made in connection with the application was false or misleading in a material particular;
- the annual charge in relation to the inclusion of the biological in the Register is not paid within 28 days of it being payable;
- the person in relation to whom the biological is included in the Register breaches a condition of the inclusion by not permitting entry and inspection etc. of a premises where the biological is dealt with or they do not provide samples of the biological as requested (subsections 32EA(1) and (3) refer);
- the person does not comply with a direction given lawfully under the Regulations to ensure compliance with the Therapeutic Goods Advertising Code in relation to an advertisement of the biological; or
- there is a breach of the advertising requirements under Part 5-1 of the Act in relation to the biological.

The decision to cancel the inclusion of the biological in the Register must be given by written notice to the person in relation to whom the biological is included.

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.

Subsection (2) explains that a notice given under subsection 32GA(1) is not a legislative instrument. This is because it relates to a specific biological and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32GB – Immediate cancellation of biological from the Register after failure to comply with information gathering notice

This section empowers the Secretary to immediately cancel from the Register a biological if she or he has given a notice, under section 32JA, to the person in respect of whom the biological is included in the Register to request information or documents about specific matters and the person either fails to give that information or they advise of certain matters in response to the request.

Subsection (1) provides that where the person is given a notice under section 32JA requiring the person to provide information of produce documents to ascertain if the biological ought to have been included in the Register and the person fails to give that information within 14 days after the period in which it is to be given the Secretary may decide to cancel the biological from the Register.

Subsection (2) provides that where the person is given a notice under section 32JA requiring the person to provide information or produce documents to ascertain if the biological is being imported, exported or supplied in Australia and the person either confirms that it isn't being imported, exported or supplied or they fail to provide information or documents on this matter within 14 days after the period in which it is due the Secretary may cancel the biological from the Register. This is because maintaining the entry in the Register is unnecessary where the person is not and does not intend to make the biological available in Australia or export it from Australia.

The Secretary is not required to give the person who is adversely affected by the decision a prior opportunity to respond to the cancellation. This is because the person has either failed to provide information in response to a notice or else has provided information indicating that inclusion in the Register is no longer required.

The Secretary is not required to cancel the entry in either of these circumstances but may do so.

Subsection (3) explains that a notice given under subsection (1) or (2) is not a legislative instrument as it relates to a specific biological and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32GC – Cancellation of biological from the Register after notice of proposed cancellation

This section empowers the Secretary, by written notice given to the person in respect of whom a biological is included in the Register, to cancel the biological's entry in the Register in certain circumstances.

Subsection (1) provides that in any of the following circumstances the Secretary may exercise this power:

- it appears to the Secretary that the quality, safety, efficacy or presentation of the biological is unacceptable;
- the biological has changed so that it is separate and distinct from what it was when included in the Register;
- the person fails to comply with a condition of the inclusion in the Register (other than entry and inspection or delivery of samples);
- the person fails to comply with a notice issued by the Secretary under section 32IA requiring information or documents to be given, within 14 days after the period the information or documents were to be given. This does not apply where section 32GB applies in relation to immediate cancellation for failure to comply with an information gathering notice;
- the person contravenes subsection 32DQ(1) and (2) for failing to notify of adverse events etc in relation to the biological. However, for this to apply it does not require that the person be convicted of the offence or be ordered to pay the civil penalty;
- the biological does not conform to a standard applicable to it (section 10 of the Act refers);
- the biological does not comply with an applicable advertising requirement under Part 5-1 of the Act or under the regulations.

Subsection (2) requires the Secretary, before cancelling the entry, to inform the person in writing that the Secretary intends to cancel the entry and provide the person with a reasonable opportunity, of not less than 28 days, to respond to the notice. Subsection (3) requires the Secretary to have regard to any submissions before a decision is made.

Subsection (4) explains that a notice given under subsection (1) is not a legislative instrument as it relates to a specific biological and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32GD – Revocation of cancellation of biological upon request
This section enables a person to apply for revocation of a cancellation they have initiated under paragraph 32GA(1)(d) within 90 days of requesting the cancellation. Where a person makes such a request it must be accompanied by the prescribed application fee to enable the administrative work involved to be undertaken in reversing the original cancellation request and returning the biological to the Register (subsection (1)).

Subsection (2) provides that where a cancellation request is revoked the cancellation is taken never to have occurred.

Section 32GE – Publication of cancellation of entry from Register
This section requires that where a biological is cancelled from the Register this must be published in a notice in the *Gazette* as soon as practicable after the cancellation occurs. The notice must set out the particulars of the cancellation.

Section 32GF – Date of effect of cancellation of entries from Register
This section provides that cancellation of a biological from the Register is effective on the day the notice is given to the person.

Division 8 – Public notification and recovery of biologicals

Section 32H – What this Division is about
This section explains that this Division is about the recovery and public notification of biologicals which do not comply with the requirements of the Act.

Section 32HA – Public notification and recovery of biologicals
Subsection (1) allows the Secretary to impose requirements on various persons set out in the table in certain circumstances set out in the table.

Subsection (2) provides that the requirements under subsection (1) may be to do one or more of the following:

- to take steps, in the specified manner and within such reasonable period as is specified, to recover biologicals that have been distributed, that is supplied into the market:
- to inform the public or specified classes of persons in a specified manner and timeframe, of the circumstances set out in subsection (1) that apply;
- to publish, in the specified manner and within a particular timeframe, certain information relating to the manufacture or distribution of the biological.

Subsection (3) provides that where circumstances identified under subsection (1) apply only to a batch of the biologicals, then the Secretary may limit the requirements provided for under subsection (2) to only the effected batch. For example if only one batch of a biological does not conform with applicable standards under the Act, the Secretary may only require that the person recover biologicals from that batch and advise relevant persons not to supply or use a biological from that batch.

Subsection (4) explains that where a biological that is the subject of a requirement under subsection (2) cannot be recovered because it has been used then the person is not required to recover that biological.

Subsection (5) explains that a notice given under subsection (1) is not a legislative instrument as it relates to a specific biological entered in the Register and administratively applies the legislation, and therefore is not legislative in character. A decision under this section is reviewable under section 60 of the Act.

Section 32HB – Publication of requirements
This section requires that as soon as practicable after the Secretary imposes a requirement under section 32HA a notice must be published in the *Gazette* setting out the particulars of the requirement.

Section 32HC – Criminal offences for non-compliance with requirements
This section establishes a tiered criminal offence regime (see pages 33 to 35) for non-compliance with the requirements applied in a notice issued under section 32HA in relation to notification and recovery of biologicals.

Subsection (1) provides that a person commits an offence if they breach a requirement imposed under section 32HA and the act or omission that caused the breach has or will cause harm or injury to any person. The penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units or both. The note under this subsection explains that a

person may, alternatively, be convicted of an offence against subsection (4) which provides a lesser penalty as there is no harm element involved.

Subsection (2) provides that a person commits an offence if they breach a requirement imposed under section 32HA and the act or omission that caused the breach is likely to result in harm or injury to any person. The penalty for an offence against this subsection is 2,000 penalty units. Subsection (3) explains that an offence against subsection (2) is a strict liability offence.

Subsection (4) provides that a person commits an offence if they breach a requirement imposed under section 32HA regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Section 32HD – Civil penalty for non-compliance with requirements
This section provides that a person contravenes this section if they breach a requirement imposed under section 32HA in relation to notification and recover of biologicals. The maximum civil penalty is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

Section 32HE – Powers of suspension and cancellation unaffected
This section provides that the power of the Secretary to suspend or cancel a biological under Division 6 or Division 7, respectively, is not affected by the imposition of a requirement under section 32HA. Recovery or recall of therapeutic goods imposed on a person under section 32HA can occur before or after the suspension or cancellation of a biological included in the Register under Part 3-2A.

Division 9 – Obtaining information or documents

Subdivision A – Preliminary

Section 32J – What this Division is about
This section explains that this Division is about obtaining information or documents in relation to applications for inclusion or biologicals in the Register, biologicals included in the Register, biologicals covered by exemptions, authorisation or approval under Division 3 of Part 3-2A.

Subdivision B – Obtaining information or documents for biologicals included or proposed to be included in the Register

Section 32JA – Secretary may require information or documents
This section empowers the Secretary, by written notice, to require a person to provide information or documents in relation to certain matters.

Subsection (1) provides that the Secretary, by written notice, may require a person to provide information or produce documents relevant to the biological. The persons to whom the Secretary may send the notice and require the information or the production of documents are the following:

- a person who has applied to include a biological in the Register;
- a person in relation to whom a biological is included in the Register; or

- a person who had (in the past 5 years) had a biological included in the Register in relation to them.

Paragraphs (1)(d) to (p) specify the matters that the information or documents required to be given or produced must relate to and include the quality, safety and efficacy of the biological, its manufacture, the regulatory history of the biological overseas, etc.

Subsection (2) requires that a person given a notice under subsection (1) must give the information or documents to the Secretary in the form specified within the time period specified in the notice which is not to be less than 14 days. The note under this subsection explains that there are applicable criminal offence and civil penalty provisions for failing to comply with a notice and for giving false or misleading information.

Subsection (3) enables the form to require or permit the information to be given or documents to be produced in accordance with specified software requirements such as on a specified kind of data processing device or to be given by way of electronic transmission, for example by email.

Subsection (4) explains that if the notice is given to a person who was previously the person in respect of whom a biological was included in the Register in the past 5 years, the types of information or documents that may be required to be given by that person under paragraphs (d) to (p) are only to be sought for the period that the person had the biological included in the Register in relation to them during that 5 year period.

Section 32JB – Criminal offences for failing to comply with a notice etc.
This section sets out the criminal offences for failing to give information or documents requested in a notice given under section 32JA or for giving false or misleading information in purported compliance with such a notice.

Subsection (1) provides that a person commits an offence if they are given a notice under section 32JA and they fail to comply with the notice. The penalty for an offence against this subsection is 500 penalty units. The note under this section is to remind readers that failure to comply with such a notice may also lead to suspension or cancellation of the biological as failure to comply provides grounds for this to occur under Division 6 or Division 7.
Subsection (1) is based upon, and is largely consistent with (including in relation to maximum penalty), existing subsection 31(4) of the Act

Subsections (2) to (5) establish a tiered criminal offence regime (see pages 33 to 35) that applies if a person provides false or misleading information in response to a request under section 32JA.
Subsection (2) provides that a person commits an offence if they are given a notice under section 32JA and they give information or produce documents in compliance or purported compliance with the notice which are false or misleading in a material particular and where the use of the biologicals has resulted in or will result, or would result in, if it were used, harm or injury to any person. The penalty for an offence against this subsection is 5 years imprisonment or 4,000 penalty units or both.

The note under this subsection explains that a person may, alternatively, be convicted of an offence against subsection (5) which provides a lesser penalty as there is no harm element involved.

Subsection (3) provides that a person commits an offence if they are given a notice under section 32JA and they give information or documents in compliance or purported compliance with the notice which are false or misleading in a material particular and where if the biologicals were used would be likely to result in harm or injury to any person. The penalty for an offence against this subsection is 2,000 penalty units. Subsection (4) provides that an offence against subsection (3) is a strict liability offence.

Subsection (5) provides that a person commits an offence if they are given a notice under section 32JA and they give information or documents in compliance or purported compliance with the notice which are false or misleading in a material particular, regardless of whether it has caused or may be likely to cause harm or injury to any person, with a maximum penalty of 12 months imprisonment or 1,000 penalty units, or both.

Section 32JC – Civil penalty for giving false or misleading information or documents in purported compliance with a notice

This section provides for a civil penalty where a person is given a notice under section 32JA and they give information or documents in compliance or purported compliance with the notice which are false or misleading in a material particular. The maximum civil penalty is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

Section 32JD – Self-incrimination
Section 32JD of the Bill deals with self-incrimination.

Subsection (1) provides that a person is not excused from giving information or producing documents under section 32JA on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty. Under subsection (2) any information or documents given in response to such a notice by an individual cannot be used as evidence against that person in criminal or civil proceedings against the person, except criminal proceedings relating to failing to comply with a notice or providing false or misleading information under subsections 32JB(1), (2), (3) or (5) or civil proceedings relating to section 32JC.

Section 32JD is based upon, and is consistent with, existing section 31F of the Act.

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.

Subdivision C – Obtaining information or documents for biologicals covered by exemptions

This Subdivision empowers the Secretary to require a person to give information or documents in circumstances where the person is covered by an exemption or the biological is covered by an exemption, authorisation or approval under Division 4. The provision in this

Subdivision reflect those provided under Subdivision B, above, in relation to biologicals that are currently, were previously or are proposed to be included in the Register.

Section 32JE – Secretary may require information etc. about biologicals exempt under the regulations

This section empowers the Secretary to require specified information or request the production of specified documents that will assist her or him to establish whether the supply, use or handling of a biological, or other matter prescribed by the regulations, covered by an exemption under section 32CA meets acceptable standards, including regulatory requirements of the Act and regulations.

The information or documents which the Secretary may require be given are in relation to one or more of the following:

- the supply (including monitoring and result of supply) of a biological;
- the use or handling of a biological; or
- other matter prescribed by the regulations in relation to a biological.

The Secretary is empowered to seek this information under subsection (1) by giving a written notice to the person who is exempted under subsection 32CA(1), from the operation of Division 4 (Inclusion of biologicals in the Register), or under subsection (2) by giving a written notice to the sponsor of a biological that is exempted under subsection 32CA(2).

Subsection (3) provides that if a person is given a notice under subsection (1) or (2) they must give the information or documents in the time period specified, which is not to be less than 14 days, and in the form specified in the notice. The note under this subsection explains that there are criminal offence and civil penalty provisions for failing to comply with a notice and for giving false or misleading information in compliance with that notice.

Subsection (4) enables the form to require or permit the information to be given or documents to be produced in accordance with specified software requirements such as on a specified kind of data processing device or to be given by way of electronic transmission.

Section 32JF – Secretary may require information etc. about biologicals exempt to deal with emergencies

This section provides powers for the Secretary to require specified information or to request the production of specified documents where biologicals are exempted under section 32CB to deal with emergencies.

The information or documents which the Secretary may require be given are in relation to one or more of the following:

- the supply (including monitoring and result of supply) of a biological;
- the use or handling of a biological; or
- other matter prescribed by the regulations.

Subsections (1) and (2) empower the Secretary to seek this information by giving a written notice to a person who is required to comply with a condition of an exemption of a biological that is exempted under section 32CB.

Subsection (3) provides that if a person is given a notice under subsection (2) they must give the information or documents in the time period specified, which is not to be less than 14

days, and in the form specified in the notice. The note under this subsection explains that there are criminal offence and civil penalty provisions for failing to comply with a notice and for giving false or misleading information.

Subsection (4) enables the form to require or permit the information to be given or documents to be produced in accordance with specified software requirements such as on a specified kind of data processing device or to be given by way of electronic transmission.

Section 32JG – Secretary may require information etc. about biologicals exempt for special and experimental uses

This section provides powers for the Secretary to require information or documents from a person who is granted an approval in relation to a biological under subsection 32CK(1) and from a person who is granted an authority under subsection 32CM(1) in relation to experimental use.

The information or documents which the Secretary may require to be given or produced under subsections (1) and (3) are in relation to one or more of the following:

- the supply (including monitoring and result of supply) of a biological;
- the use or handling of a biological; or
- other matter prescribed by the regulations.

The Secretary is empowered to seek this information or the production of a document under subsection (1) by giving a written notice to a person who is granted an approval under subsection 32CK(1) in relation to a biological, and under subsection (3) by giving a written notice to a from a person who is granted an authority under subsection 32CM in relation to a biological.

Subsection (2) empowers the Secretary to seek information from a person (known as the ***experimenter***) who uses a specified biological that is the subject of an approval held by another person under subsection 32CK(1) for the import or supply of the biologicals for solely experimental purposes in humans. Under this subsection the information that may be required is in relation to the use of the biological and any other matter prescribed by the regulations.

Subsection (4) provides that if a person is given a notice under subsection (1), (2) or (3) they must give the information or documents in the time period specified, which is not to be less than 14 days, and in the form specified in the notice. The note under this subsection explains that there are criminal offence and civil penalty provisions for failing to comply with a notice and for giving false or misleading information.

Subsection (5) enables the form to require or permit the information to be given or documents to be produced in accordance with specified software requirements such as on a specified kind of data processing device or to be given by way of electronic transmission.

Section 32JH – Secretary may require information etc. about biologicals exempt where substitutes are unavailable etc.

This section provides powers for the Secretary to require information from a person who is granted an approval under subsection 32CO(1) or (2) in relation to a biological for which substitutes are not available or are in short supply.

The information or documents which the Secretary may require to be given or produced are in relation to one or more of the following:

- the supply (including monitoring and result of supply) of a biological;
- the use or handling of a biological; or
- other matter prescribed by the regulations.

The Secretary is empowered to seek this information under subsection (1) by giving a written notice to the person who is granted an approval under subsection 32CO(1) or (2) in relation to a biological.

Subsection (2) provides that if a person is given a notice under subsection (1) they must give the information or documents in the time period specified, which is not to be less than 14 days, and in the form specified in the notice. The note under this subsection explains that there are criminal offence and civil penalty provisions for failing to comply with a notice and for giving false or misleading information.

Subsection (3) enables the form to require or permit the information to be given or documents to be produced in accordance with specified software requirements such as on a specified kind of data processing device or to be given by way of electronic transmission.

Section 32JI – Criminal offences for failing to comply with a notice etc.
This section sets out the criminal offences where a person fails to comply with a notice requiring that information or documents be given under section 32JE, 32JF, 32JG or 32JH. It is based upon existing sections 31C and 31E of the Act.

Subsection (1) provides that a person given a notice under section 32JE, 32JF, 32JG or 32JH commits an offence if they fail to comply with such a notice. The penalty for an offence against this subsection is 500 penalty units.

Subsection (2) provides that a person commits an offence if they give information in compliance or purported compliance with such a notice that is false or misleading in a material particular. The penalty for an offence against this subsection is 12 months imprisonment or 1,000 penalty units or both.

Section 32JJ – Civil penalty for giving false or misleading information or document in purported compliance with a notice
This section provides for a civil penalty where a person is given a notice under section 32JE, 32JF, 32JG or 32GH and they give information or documents in compliance or purported compliance with the notice which are false or misleading in a material particular. The maximum civil penalty is 5,000 penalty units for an individual or 50,000 penalty units for a body corporate.

Section 32JK – Self-incrimination
Section 32JK of the Bill deals with self-incrimination.

Subsection (1) provides that a person is not excused from giving information or producing documents under sections 32JE, 32JF, 32JG or 32JH on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

Under subsection (2) any information or documents given in response to such a notice by an individual cannot be used as evidence against that person in criminal or civil proceedings against the person, except proceedings for an offence against subsection 32JI(1) or civil proceedings against section 42Y for the contravention of section 32JJ.

This section is based upon, and is consistent with, existing section 31F of the Act.

It 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.

Subdivision D – Inspecting, copying and retaining documents

This Subdivision empowers the Secretary to inspect, make copies of and retain documents or copies of documents given in response to a notice requiring that they be given under Subdivision C, explained above.

Section 32JL – Secretary may inspect and copy documents
This section empowers the Secretary to inspect a document that is given in response to a notice requiring the document to be given under section 32JA, 32JE, 32JF, 32JG or 32JH. The Secretary may also make copies of the document (either in whole or part) and keep those copies.

Section 32JM – Secretary may retain documents
Subsection (1) section empowers the Secretary to keep a document that is given under section 32JA, 32JE, 32JF, 32JG or 32JH for as long as necessary.

Subsection (2) provides that a copy of the document be given as soon as practicable to the person who would normally be in possession of the document. That copy must be certified by the Secretary as a certified copy, and under subsection (3) must be received in evidence in courts as if it was the original. Until such a copy can be provided the person, or a person authorised by them, must be given reasonable access to the document to inspect it and make copies (subsection (4)).

Item 26
This item inserts new section 33B after section 33A in the Act to provide that Part 3-3 of the Act, which provides for the manufacturing of therapeutic goods, is not to apply to Class 1 biologicals. 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.

Items 27 and 28
These items exempt biologicals, which are the subject of an exemption for emergency purposes under section 32CB, from the criminal offence provisions relating to manufacturing under subsections 35(1), 35(2), 35(4) and 35(5) of the Act. This is consistent with the application of these offence provisions to therapeutic goods exempted for emergency purposes under existing section 18A of the Act.

Item 29
This item exempts biologicals, which are the subject of an exemption for emergency purposes under section 32CB, from the civil penalty provisions relating to manufacturing under subsections 35A(1) and 35A(2) of the Act. This is consistent with the application of these penalty provisions to therapeutic goods exempted for emergency purposes under existing section 18A of the Act.

Item 30
This item adds new subsection (3) at section 39 of the Act, relating to the term of a manufacturing licence for a biological exempted for emergency purposes.

The new subsection provides that a licence for the manufacture of a biological that is exempt under section 32CB ceases to be in force in relation to the manufacture of that biological when the biological ceases to be exempt under that section. The note under this new subsection explains that an exemption under section 32CB may cease to have effect only in relation to some of the biologicals covered by that exemption (as it may cover more than one biological), subsections 32CB(5) and 32CD(1) refer.

This is consistent with the term of a manufacturing licence for therapeutic goods exempted under existing section 18A for emergency purposes provided under subsection 39(2).

Item 31
This item replaces paragraph 40(4)(a) in relation to conditions imposed on manufacturing licences to reflect biological therapeutic goods, including supply and export of biologicals under the exceptional release scheme.

The effect of the new paragraph 40(4)(a) is that in addition to any conditions imposed under subsections 40(1) or (2), a licence (except as otherwise specified in the licence) is subject to the condition that the holder of the licence will ensure that the goods conform to any applicable standard and will observe the applicable manufacturing principles in undertaking to manufacture goods under the licence. This does not apply if the goods are biologicals and are for supply after the circumstances prescribed in the circumstances by the regulations for the purposes of paragraph 14(9A)(b) and subsection 14A(2A) have occurred, or the goods are biologicals and are for export after the circumstances prescribed by the regulations for the purposes of paragraphs 14(13A)(b) and 14A(3A) (b) have occurred.

This is because under exceptional release the biologicals may not meet the applicable standards for the biologicals or their manufacture (items 18 to 22 refer).

Item 32
This item inserts new paragraph (ga) at subsection 41(1) after paragraph (g) of the Act, in relation to revocation and suspension of manufacturing licences. The new paragraph empowers the Secretary to revoke or suspend a manufacturing licence if the licence is for the manufacture of a biological exempted for emergency purposes under section 32CB and the holder of the licence has breached a condition of the exemption in relation to the exempted biological. The revocation or suspension must be advised by notice in writing given to the holder of the manufacturing licence and if the licence is being suspended the period of the suspension is to be specified in the notice.

This new paragraph does not require that the Secretary revoke or suspend the manufacturing licence.

Item 33
This item inserts new section 41BJA after section 41BJ of the Act. Subsection (1) provides that, subject to provisions in the section, Chapter 4 of the Act is not to apply to biologicals (subsection 41BJA).

Subsection (2) provides that, if before this new section commences biologicals are included in the Register as medical devices, under Chapter 4, that Chapter will continue to apply to the biological until the biological is moved to that part of the Register for biologicals under new Part 3-2A. The note at the bottom of this subsection explains that section 32DN deals with transitioning biologicals from parts of the Register to that part of the Register for biologicals.

Subsection (3) provides that applications to include goods in the Register as a medical device that are biologicals under Part 3-2A, are to continue to be dealt with under Chapter 4 until one of the following occur:

- the therapeutic good is included in the part of the Register for biologicals under Part 3-2A (section 32DN refers);
- the application is unsuccessful when it is finally determined;
- the application is withdrawn;
- the application lapses.

Subsection (3) only applies if the application for inclusion of a biological in the Register under Chapter 4 of the Act was made before the commencement of this section, and that application had neither been finally determined nor withdrawn before that commencement.

Subsection (4) defines ***finally determined*** and provides for any possible reviews and appeals arising out of the decision to be completed and exhausted. This is consistent with the definition under section 32DN.

Subsections (5) and (6) provides that where biologicals become included in the Register under Part 3-2A that they were previously included under Chapter 4 or where an application was made under Chapter 4, that Chapter continues to apply to the biological in relation to things done or not done while it was regulated under Chapter 4.

Item 34
This item inserts new paragraph (fa) after paragraph 42DL(1)(f) in relation to advertising offences.

The new paragraph prohibits a person from publishing or broadcasting an advertisement about therapeutic goods that contains a statement about a biological other than a statement that has been authorised or required to be made by a government or government authority. The penalty for an offence against this paragraph is 60 penalty units.

This is necessary as it is inappropriate for biologicals to be advertised as the nature of the good means that they are only suitable to be supplied and used by appropriately qualified healthcare professionals and, therefore, it is not necessary or appropriate for them to be advertised to the public. The provision of information about these goods can be made to

healthcare professionals and other relevant professionals, including through advertisements in professional publications, under section 42AA of the Act.

Item 35
This item amends subsection 42V(7) to extend it to include those new Divisions for the cancellation or suspension of biologicals and new section 29D for the suspension of registered and listed goods. The amendment to this subsection to provide for new section 29D is consequent to the new section being included in the Act by the *Therapeutic Goods Amendment (2009 Measures No 1) Act 2009* and this consequential amendment was inadvertently not made at that time.

As a result of the amendment, the operation of section 42V in relation to recovery of therapeutic goods because of actual or potential tampering does not prevent the Secretary from taking action to:

- suspend or cancel registered or listed goods from the Register under sections 29D or 30 of Part 3-2 of the Act, respectively;
- suspend or cancel medical devices from the Register under Divisions 1 or 2 of Part 4-6 of the Act, respectively; or
- suspend or cancel biologicals from the Register under Divisions 6 or 7 of Part 3-2A of the Act, respectively.

Item 36
This item amends section 46A, which empowers an authorised person under the Act to enter premises, search those premises, take samples, make measurements and test, take moving or still images and inspect any book, record or documents in the premises. These entry and search powers can be exercised subject to certain restrictions and are for the purpose of finding out whether the Act or Regulations have been complied with by relevant persons in relation to specified premises.

This item inserts three new subparagraphs after subparagraph 46A(4)(a)(ii), in relation to searches of certain premises to monitor compliance with the Act. The new subparagraphs extend the application of this section to premises of a person who is any one of the following:

- required to comply with a condition of an exemption of a biological that is exempted under section 32CB;
- has been granted an approval under subsection 32CK(1) for special and experimental uses of a biological;
- a medical practitioner who has been granted an authority to supply specified biologicals for the treatment of humans under subsection 32CM(1);
- has been granted an approval under subsection 32CO(1) or (2) to use a biological to substitute for a therapeutic good that is included in the Register where such a good is unavailable or in short supply, or where no good in the Register is suitable.

Item 37
This item inserts new paragraph 53(ba) to extend the current power under that section to retain material submitted with an application for inclusion of a therapeutic good in the Register, where the application is withdrawn, to cover applications for inclusion of a biological in the Register.

Item 38
This item inserts ten table items, after current table item 13, setting out the alternative verdicts that a person may be convicted of in relation to offences relating to biologicals.

Items 39 to 42
Section 56A provides for the Secretary or a person authorised in writing by her or him to certify certain matters. These items extend section 56A to apply to matters in relation to biologicals.

The new paragraphs provide that the Secretary or a person authorised in writing by her or him can give certificates certifying, in writing, that at specified time or at times during a specified period:

- a person was not exempt under subsection 32CA(1) in relation to a particular biological or the biological was not exempted under subsection 32CA(2);
- an exemption for emergency purposes was not in effect under section 32CB in relation to a particular biological;
- there was no approval under subsection 32CK, for special and experimental uses of biologicals, or authority granted to a particular medical practitioner in relation to a particular biological under section 32CM;
- there was no approval granted to a particular person in relation to a particular biological under subsection 32CO(1) or (2), to use a biological to substitute for a therapeutic good that is included in the Register where such a good is unavailable or in short supply, or where no good in the Register is suitable;
- a particular biological was either included or not included in the Register.

Items 43 to 47
These items amend section 57 in relation to delegation of the Minister's and Secretary's powers under the Act.

These amendments insert into the existing delegation provisions, authorisation and approval powers for biologicals that correlate to those already provided for under this section for other therapeutic goods so approved or authorised.

Item 43 amends paragraphs 57(2) and (3) provides that the Secretary may delegate her or his power under paragraph 32CK(1)(d) to approve the use of a biological that is not included in the Register for solely experimental purposes in humans to a person specified in those subsections.

Item 44 amends paragraph 57(5)(b) to extend it to cover approvals to use biologicals for experimental purposes in humans made under paragraph 32CK(1)(d) so that the regulations made for the purposes of subsection (3) may cover such delegated approvals.

Item 45 amends subsections 57(6) and (7) to extend them to who the Secretary may delegate her power under section 32CM(1), for authorising certain medical practitioners to use certain biologicals that are not included in the Register, and enabling regulations to be made to prescribe the circumstances and requirements subject to which such delegation may be made.

Item 46 amends subsection 57(8) to extend this to apply to approvals where substitutes of biologicals are unavailable, in short supply, or similar circumstances, under section 32CO.

Item 47 inserts new subsection 57(10A) after subsection (10) to provide that the power of the Minister under subsection 32CB(1), to exempt biologicals for emergency purposes, may be delegated only to the Secretary.

Item 48
This item repeals subsection 59(3) as paragraph section 63(3)(b) of the Act already allows for the making of regulations to provide for the waiving of fees and as a result this subsection is no longer required. The waiver of fees applicable to particular bodies can be prescribed in the Regulations.

Item 49
This item inserts new paragraph 60(1)(ca) after paragraph (c) of the definition of ***initial decision*** to provide that decisions under Part 3-2A of the Act for biologicals are to be taken to be initial decisions for the purposes of review of decisions.

Items 50 to 53
These items amend section 60A, in relation to new information on review of a decision, so that this section provides for relevant provisions under Part 3-2A for biologicals.

Item 50 amends subsection 60A(1) to provide that section 60A covers decisions made by the Secretary or delegate under sections 32DF and 32DG to include Class 1 and other classes of biologicals in the Register, respectively.

Item 51 inserts new subsection 60A(6AA) after subsection (6). This provides that if a matter relates to a decision to include, or refuse to include, a biological in the Register and the Minister or Tribunal remits it to an authorised delegate for a fresh decision and the appellant has paid a further evaluation fee, reflecting that that information not provided with the application is sought to be considered, then the authorised delegate must make that fresh decision taking into account both the initial new information and / or later new information.

Item 52 amends subsection 60A(7) to extend the scope of this subsection to provide that delegate's fresh decisions are to be treated as having been made as a decision under new Part 3-2A in the Act for biologicals.

Item 53 inserts new paragraph 60A(8)(aa) after paragraph (a) to extend the definition of ***authorised delegate*** to include a delegate of the Secretary exercising a power to decide whether to include a biological in the Register. Item 16 in Schedule 6 of this Bill also amends the definition of ***authorised delegate***. The amendment made by this item is consequential to the amendment made by item 16 in Schedule 6, and will only take effect from the commencement of this Schedule which will be after the commencement for Schedule 6.

Item 54
This item amends subsection 61(3A) to provide that the power of the Secretary to release information, to specified persons or authorities, that has been obtained in response to a notice given to a person regarding goods exempted, authorised or approved under the Act, is extended to include information from notices given under sections 32JE, 32JF, 32JG and 32JH regarding biologicals exempted from the requirements to be included as a biological under Part 3-2A of the Act.

Item 55
This item inserts a new paragraph 61(4)(baa) after paragraph (b) to provide that the Secretary may release information, to a national regulatory authority of another country, in relation to decisions on the inclusion of biologicals in the Register or the suspension or cancellation of biologicals from the Register. This is consistent with the Secretary's power in relation to other therapeutic goods under subsection 61(4).

Item 56
This item extends subsection 61(10), in relation to protection of information where the disclosure of it would constitute a breach of the Mutual Recognition Convention, to provide that information referred to in subsection 25(2E) of the Act in relation to overseas manufacture evaluation and assessment by recognised agencies includes information which relates to overseas evaluations and approvals of the manufacture of biologicals (as that section applies to biologicals because of subsections 32DE(2) and 32EB(3)).

Item 57
This item inserts new paragraph 63(2)(daa) after paragraph (da) to provide that regulations may be made to provide for the periods within which evaluations of specified biologicals or classes of biologicals (other than Class 1 biologicals as they are assessed rather than evaluated) are to be completed. Where an evaluation exceeds such a period, if specified, section 32DM providing for a reduction in evaluation fee payable by the applicant applies.

Item 58
This item explains that the amendment made by item 31 applies to manufacturing licences granted before, on or after the commencement of that item. Therefore, from the commencement of item 31, the licence condition that goods manufactured comply with standards applicable to those goods and that the holder of the licence observes the manufacturing principles in the manufacture of those goods, continue to apply to the manufacturer of biologicals except where the biologicals meet the exceptional release requirements prescribed in the Regulations.

Item 59
This item sets out the transitional arrangements for biologicals exempted under paragraph 18(1)(c) the Act (as a medicine or therapeutic device) before the commencement of this item.

Under sub-items (2) and (3) such exempted biologicals are to be taken to be covered by a ***transitional exemption*** under new subsection 32CA(2) for a period of 3 years beginning on the day this item commences or until the exemption ceases.

Sub-item (4) provides that if a person applies to include the exempted biological in the Register under new section 32DA or 32DD within 18 months of the transitional exemption starting, and the application is not dealt with within the 3 year transitional exemption period, the transitional exemption is extended until a decision on the application is made and notified to the person.

The purpose of sub-item (4) is to provide an incentive for persons in respect of whom a biological is covered by a transitional exemption to make an application for the inclusion of the biological in the Register within 18 months of the new arrangements for biologicals commencing.

Where a person makes an application after 18 months of the transitional exemption commencing then the normal evaluation period specified in regulations to be made under new paragraph 63(2)(daa) (item 60 refers) will apply. If a decision is not made on the application until after the 3 year exemption period has expired then the biological ceases to be able to be imported, exported, supplied or used (as the case may be) for the period between the transitional period ending and the biological being included in the Register (if the decision is to include the biological) unless the biological becomes exempted under another provision in Part 3-2A.

Sub-item (5) provides that if a person makes an application for the inclusion of the biological covered by a transitional exemption in the Register and a decision on the application is made within the transition period, the transitional exemption in relation to that biological ceases immediately after the applicant is notified of the decision.

The transition period is to provide sufficient time for industry to make any changes necessary to comply with the new requirements and is consistent with the timeframe set out in the biologicals framework proposal (then known as the Human Cell and Tissues framework) that was endorsed by Australian Health Ministers' Advisory Council's in October 2006.

Item 60
This item provides for the Governor-General to make regulations prescribing matters in relation to transition of biologicals across to the new regulatory framework provided in this Schedule to the Bill.

SCHEDULE 2 – Immunity from civil actions

Therapeutic Goods Act 1989

At present the Act contains a number of provisions conferring immunity from civil action on Commonwealth, the Minister and/or the Secretary in respect of loss, damage or injury of any kind suffered by a person as a result of, or arising from, the use of particular therapeutic goods or as a result of, or arising from, particular decisions taken under the Act or under the Regulations, made under the Act.

However, the coverage and the immunity from civil actions set out in each of those provisions differ. Some of these immunity provisions specifically protect the Commonwealth, while others do not refer to it. Some immunity provisions are more broadly expressed, do not refer to the liability of specific officers and do not specify a failure by a specific person. In contrast, some immunity provisions are expressed narrowly by only referring to the decision-maker (e.g. the Secretary or her delegate).

In some circumstances, decisions-makers under the Act and Regulations rely on the input of other TGA officers and advisory committees established under the Act or the Therapeutic Goods Regulations 1990. However, these persons are not specifically referred to in the immunity provisions, meaning that they could be liable for a civil suit, proceeding or action while the decision-maker is not.

The purpose of the amendments in this Schedule is to provide a consistent immunity from civil actions, suit or proceedings to the Commonwealth or a protected person, in respect of loss, damage or injury of any kind suffered by another person as a result of anything done, or omitted to be done by a protected person in the performance or the exercise of their functions, duties or powers under the Act and Regulations. Protected persons under the Act and Regulations include the Minister, the Secretary, delegates of the Minister or the Secretary, members of statutory advisory committees and authorised persons or officers under the Act and Regulations. However, the immunity from civil action against the Commonwealth and protected persons does not apply to an act or omission by the protected person in bad faith.

The amendments in this Schedule also repeal the existing specific immunity provisions.

Items 1, 2 and 4 to 13
These items repeal the existing immunity provisions at subsections 18A(12), 19(8), 25(4A), 25(6), 25A(4), 26(1B), 26A(1B), 41ED(2), 41HC(6), 61(9) and section 41GX. As a result of the repeal of subsection 41ED(2), subsection 41ED(1) is reformatted by item 9.

Item 3
This item amends subsection 25(1) to make it clear that the Secretary is responsible for evaluating goods for registration. (The current provisions do not refer to a particular person to carry out the evaluation of the therapeutic goods for registration under section 25 of the Act.)

Item 14
This item inserts a new section 61A providing a general immunity provision to the Commonwealth or a protected person. This provision is modelled on those in the *Quarantine Act 1908* (section 82), *Imported Food Control Act 1992* (section 38) and the *Australian Prudential Regulation Authority Act 1998* (section 58).

Subsection (1) provides that no civil action, suit or proceeding lies against the Commonwealth or a protected person in respect of any loss, damage or injury suffered by another person as a result of anything done – or omitted to be done – by a protected person in relation to their performance, or exercise of their functions, powers or duties under the Act or the Regulations. The immunity extends to the purported performance or purported exercise of a protected person's functions, powers or duties under the Act or the Regulations.

Subsection (2) provides that the protection from civil action, suit or proceeding by the Commonwealth or a protected person as set out in subsection (1) does not apply to an act or omission in bad faith. Therefore the person who has commenced the civil action, suit or proceeding against the Commonwealth or a protected person must prove that the act or omission is in "bad faith".

Subsection (3) provides that a reference in subsection (1) to anything omitted to be done includes a reference to a failure to make a decision. This would cover circumstances, for example, where the Secretary has failed to make a decision on an application for a conformity assessment certificate, or the evaluation of a therapeutic good within the prescribed time in the Regulations.

Subsection (4) provides that for the purposes of this section, a ***protected person*** is the Minister, the Secretary, a person to whom powers or functions are delegated under subsection 57(1) of the Act, a member of a committee established under the Act or the Regulations, an authorised person in relation to any other provision of the Act, an authorised officer (within the meaning of the Regulations), an authorised person within the meaning of the Regulations, and a person assisting those persons listed previously (the ***primary person***) in relation to the performance or purported performance, or in relation to the exercise or purported exercise, of a primary person's functions, duties or powers under the Act or the Regulations.

Ancillary or incidental acts
The immunity to civil action under subsection 61A(1) includes acts (or omissions) that are ancillary or incidental to the performance or exercise of functions, powers or duties under the Act or Regulations. The combination of subsections 61A(1) and (4) has the effect of extending the acts and omissions to those that are ancillary or incidental to the performance (or purported performance) or exercise (or purported exercise) of functions, powers or duties under the Act and Regulations. This legal effect is achieved by the combination of the following:

(a) the list of protected persons, in particular, paragraphs 61A(4)(d) to (h) in the definition of a protected person;
(b) the wording of subsection 61A(1) referring to "in relation to the performance or purported performance, or in relation to the exercise or purported exercise"; and
(c) the use of the phrase "a protected person's" in subsection 61A(1).

For example, a person who is collating, analysing and providing a summary to enable a function to be carried out under the Act is within the definition of a protected person and is doing or has done something “in relation” to the performance by another protected person of such a function.

Item 15

This item provides that the new section 61A (item 14 refers) applies to any act or omission after the commencement of item 14 (i.e. the day after Royal Assent).

Item 16

This item provides that despite the repeal of existing immunity provisions under items 1 to 2 and 4 to 13, those provisions continue to apply to any act or omission before these provisions were repealed.

SCHEDULE 3 – Recall of therapeutic goods

Therapeutic Goods Act 1989

Item 1
This item amends the table in subsection 30EA(1) to allow the Secretary to require a person in relation to whom goods are included in the register to take steps to recall the goods if it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable or that the presentation of the goods is unacceptable. Under the current provision the Secretary can only require a recall in other specified circumstances, but there is no power to initiate a recall for unacceptable quality, safety, efficacy or presentation in and of themselves.

Item 2
This item amends the table in subsection 41KA(1) to allow the Secretary to require a person in relation to whom a kind of medical device is included in the register to take steps to recall the medical device if it appears to the Secretary that the quality, safety or performance of the device is unacceptable. Under the current provision the Secretary can only require a recall in other specified circumstances, but there is no power to initiate a recall for unacceptable quality, safety or performance in and of themselves.

Item 3
This item provides that the amendments made by items 1 and 2 apply to goods and devices included in the Register at any time.

SCHEDULE 4 – Information gathering

Therapeutic Goods Act 1989

Items 1 to 5
These items amend section 31 which deals with obtaining information relating to therapeutic goods. At present section 31 authorises the Secretary, by notice in writing, to obtain information or documents from a person who has applied to register or list goods, or a person in relation to whom goods are registered or listed. However, section 31 currently does not authorise the Secretary to request information from persons who were persons in relation to whom goods are registered or listed but no longer are.

In contrast, section 41JA of the Act, authorises the Secretary, by written notice given to a person (in relation to whom a kind of medical device, is or was at any time during the notice period under subsection 41JA(2), included in the Register) to require that person to give to the Secretary, particular information or documents relating to devices of that kind.

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.

Item 1
Item 1 amends subsection 31(1) dealing with registered goods by extending the Secretary's power to obtain information or documents from a person in relation to whom goods were registered at any time during the five years prior to the notice being given.

Subsection 31(1) of the Act currently authorises the Secretary to give written notice to a relevant person (an applicant for registration or in relation to whom therapeutic goods are registered) requiring that person to give to the Secretary, within such reasonable time as is specified in the notice, information or documents relating to matters set out in paragraphs 31(1)(a) to (k).

This information or document includes the formulation of the goods, composition of the goods, quality of the goods and design specification of the goods. The period or the time that the person is required to comply with the notice is not specified in these provisions. Instead, the person is required to comply within such reasonable time as specified in the notice. Setting a minimum period would limit the Secretary's ability to obtain timely information and potentially prejudice public health and safety.

This item amends this section to enable information to also be sought from a person who previously was the person in respect of whom a good was registered under the Act (often referred to as the sponsor). This is necessary where the registration of a product is transferred to a different sponsor and there are, for example, concerns regarding past batches of the good for which the current sponsor is unable to provide information or documents.

The amendment limits the past sponsors who can be required to provide information to those that were the sponsor at any time during the previous five years prior to the notice being given. Item 2 limits the information about the registered good that can be sought.

Item 2
Item 2 inserts a new subsection 31(1A). This new subsection limits the information which can be sought under subsection 31(1) from a person covered by new paragraph 31(1)(ac), that is a person who was a past sponsor of a registered good (item 1 refers).

The new subsection provides that if a notice is given under subsection 31(1) to require information or documents from a person who was a past sponsor of a registered good, then only the documents or information relating to the matters set out in paragraphs 31(1)(a) to (k), to the extent to which they are relevant, can be required to be provided and only in relation to the part of the period of five years before the notice was given during which the therapeutic goods were registered.

Item 3
Item 3 amends subsection 31(2) dealing with listed goods by extending the Secretary's power to obtain information or documents from a person in relation to whom the goods were listed at any time during the previous five years. This amendment is similar in scope to the amendments set out in item 1 but applies to listed goods and to persons covered by new paragraph 31(2)(ac), i.e. persons in respect of whom goods were previously listed in the Register (often referred to as the sponsor).

Item 4
Item 4 inserts new subsection 31(2A), which provides that if a notice is given under subsection 31(2) to a person who was a past sponsor of a listed good, then the documents or information relating to the matters set out in paragraphs 31(1)(a) to (k), to the extent to which they are relevant, can be required to be provided and only in relation to the part of the period of five years before the notice was given during which the therapeutic goods were listed.

It should be noted that section 31 of the Act differs from information gathering powers in other statutes by not requiring the Secretary to form a reasonable belief that a person has relevant information before issuing a notice seeking the information.

The Secretary may request information or documents during the evaluation of the safety, efficacy, or quality of the goods. During this process, the Secretary may not be satisfied that the information lodged with the application for registration fully supports the application. As a result, the Secretary may request additional information from the sponsor. The sponsor may or may not have this additional information. If the sponsor is not able to provide the supporting information needed then the application may be rejected.

The Secretary is not required to form a reasonable belief that the sponsor has the relevant information; rather what is required is that, in approving the registration, the Secretary must be satisfied that the criteria for registration as set out under section 25 of the Act are satisfied.

In addition, there may circumstances wherein the Secretary may request information or documents in relation to investigations regarding the safety of certain medicines and it is possible that not all sponsors of the equivalent medicines may hold this information.

Furthermore, persons who are or were sponsors of therapeutic goods are inherently likely to have relevant information or other documents and, thus, the information gathering powers can only apply to these persons and not others. Therefore, to require the Secretary to form a reasonable belief that a person has relevant information before issuing a notice seeking the information or documents may, in some cases, be too restrictive.

Section 31 as amended is now substantially similar to the information gathering power authorised under section 41JA of the Act.

Item 5

Item 5 recasts subsection 31(4) to align with current drafting policy on the drafting of offence provisions. The elements of the current offence and the offence as redrafted are identical. The penalty level of 500 penalty units is the same as the existing provision. A high monetary penalty is required to ensure compliance and deterrence, in particular as the information or document required relates to information about the quality, safety, efficacy and presentation of the goods which are necessary to ensure decisions made, or to be made, would not prejudice public safety.

Item 6

This item provides that the amendments made by items 1 to 5 apply in relation to notices given on or after the commencement of those items (i.e. the day after Royal Assent), and that new paragraphs 31(1)(ac) and 31(2)(ac) of the Act apply in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of this item. (i.e. the day after Royal Assent)

SCHEDULE 5 – Unpaid annual charges

Therapeutic Goods Act 1989

The Act requires that a therapeutic good must be registered, listed or included in the Register before it can be lawfully imported into, manufactured in, supplied in, or exported from Australia. In addition, the Act generally requires a person to obtain a manufacturing licence to manufacture goods in Australia. An annual charge is payable in respect of the registration, listing or inclusion of therapeutic goods in the Register, and in respect of manufacturing licences issued under the Act.

Annual charges are considered to be taxes and, in accordance with section 55 of the Constitution, are imposed by a separate taxing Act: the *Therapeutic Goods (Charges) Act 1989* (the Charges Act). The provisions relating to the assessment, recovery and collection of the annual charges are contained in the Act.

This Schedule amends the Charges Act to provide for annual charges to be payable in respect of the inclusion of biologicals in the Register and to provide that where a registered or listed therapeutic good or a biological is suspended from the Register, the Charges Act continues to apply to the good as if it were not suspended from the Register. This reflects that the good remains regulated by the TGA while it is suspended and the annual charge, therefore, remains payable.

Item 1

This item inserts new section 44B, providing that an annual charge that remains unpaid for 28 days after the day on which it becomes payable may be recovered by the Commonwealth as a debt due to it.

The note refers readers to section 44 of the Act which sets out the dates when annual charges for registered, listed or kinds of medical devices included in the Register, and annual licensing charge are payable. Subsection 44(3) of the Act allows the Secretary to specify a later day on which the annual charge becomes payable by a person for a financial year. The change in date is notified by the Secretary, in writing, to that person and the notice has effect accordingly.

Item 2

This item provides that the amendment made by item 1 applies to annual charges that become payable after that item commences (i.e. the day after Royal Assent).

SCHEDULE 6 – Other amendments

Therapeutic Goods Act 1989

Item 1
This item makes a technical amendment to the definition of ***therapeutic goods*** in subsection 3(1) to update an old reference to a food standard under the *Australia New Zealand Food Authority Act 1991* with a reference to a standard under the *Food Standards Australia New Zealand Act 1991*.

Item 2
This item amends paragraph (f) of the definition of ***therapeutic goods*** in subsection 3(1).

The current definition excludes, at paragraph (f), goods which in Australia or New Zealand have a tradition of use as foods for humans in the form in which they are presented. This means that any product or goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented, are not therapeutic goods.

The amendment to paragraph (f) of the definition has the effect of authorising the Secretary to declare goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented, to be therapeutic goods under section 7 of the Act.

Item 3
This item amends subsection 28(3A) to provide that a fee may be charged for considering a request to vary the conditions of registration or listing for a medicine. This provision will support the introduction of risk management plans for registered medicines as a condition of registration under section 28 of the Act.

Until recently the TGA's oversight of registered medicines has combined extensive pre-market evaluation with essentially reactive post-market issues management. While a new medicine is registered on the basis that for the specified indication and target population the benefits outweigh the risks, not all actual or potential risks will have been identified when registration is sought.

The TGA is now refocussing its effort to provide regulation throughout a product's life-cycle. As part of this approach it may require sponsors of certain higher risk medicines to comply with an approved risk management plan as a condition of registration.

As a medicine is used more widely, more information about its safety and efficacy becomes available. In some instances, information gathered by the sponsor may prompt the sponsor to apply to the TGA to vary the risk management plan, and hence the conditions of registration, for a medicine. Before agreeing to vary the conditions of registration, the TGA would need to evaluate the new information and make a decision on whether the variation sought by the sponsor is appropriate. The amendment made by this item allows the TGA to impose a fee to cover the cost of this activity.

Items 4 and 5
These items amend subsection 42DL(1). At present the section establishes an offence for publishing or broadcasting an advertisement that refers to goods included in Schedules 3, 4 or

8 of the Poisons Standard (covering substances which may only be dispensed after advice from a pharmacist, substances which may only be dispensed on prescription, and drugs of dependence which may only be dispensed on prescription and have other conditions attached).

However, this precludes persons wishing to advertise other therapeutic goods, such as complementary medicines, from including in advertisements warnings about interactions with Schedule 3, 4 or 8 medicines that must be included on the labels of the complementary medicines under an order made by the Minister under section 10 of the Act.

The amendment addresses this by permitting statements to be included in an advertisement that refer to medicines set out in Schedule 3, 4 or 8 of the current Poisons Standard if the statement is authorised or required by a government or government authority. The authorisation or requirement can also be by a foreign government or a foreign government authority.

Item 6
This item makes a technical amendment to update two old references to the 'Poisons Standard' in subsections 42DL(2) and (3) with a reference instead to the 'current Poisons Standard'.

Item 7
This item inserts a new paragraph after subsection 57(1) of the Act. Paragraph 57(1)(d) adds to the range of persons to whom the Minister or Secretary may delegate any of their powers or functions under the Act. Paragraph 57(1)(d) now authorises the Secretary or the Minister to delegate any of their powers or functions under the Act to persons seconded to the Department from state or territory authorities, a national regulatory authority of a foreign country or international organisations that have functions or responsibilities relating to therapeutic goods, health or law enforcement.

The TGA is one of the leading therapeutic goods regulators in the world and has memoranda of understanding with a number of other national regulatory agencies of other countries that provide inter alia for the exchange of information or staff. These exchanges are usually at a senior level, and the staff involved occupy positions that require the exercise of powers under the Act to fulfil them.

Items 8 to 19
These items amend section 60A which deals with the circumstances under which the Minister (when reviewing an initial decision under sections 25 or 41EC) or the Administrative Appeals Tribunal (AAT), reviewing a reconsideration made by the Minister of an initial decision under section 60 of the Act) may or may not take into account additional information supplied by an applicant.

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.

New information is currently defined as information that:

(a) was in existence at the time the decision referred to in subsection 60A(1) was made; and
(b) was not made available to the Secretary or authorised delegate for the purpose of making the decision; and
(c) is relevant to the decision,

and includes any opinions that are wholly or substantially based on such information (whether or not he opinions were formed before or after the decision was made.)

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).

Items 8 and 9

Item 8 replaces the reference in subsection 60A(2) to "new information" with a reference to "initial new information" that may be considered by the Minister. Item 9 replaces the reference in subsection 60A(3) to "new information" with a reference to either or both "initial new information" and "later new information", allowing the AAT to remit the matter to the TGA if either is provided in the relevant decision-making.

Item 10

Item 10 repeals and replaces subsection 60A(4) to provide that if the AAT is provided with "initial new information" by the appellant and not "later new information" it must not remit the decision if the initial new information had been considered by the Minister as part of the reconsideration of the initial decision (as defined under section 60 of the Act).

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.

Item 11

Items 11 to 14 amend subsection 60A(5) allowing the AAT to consider initial new information considered by the Minister on reconsideration, but not allowing it to consider any other "initial new information" or "later new information" unless it is information that indicates that the quality, safety or efficacy of the goods in unacceptable.

Item 15

Item 15 includes consequential amendments to subsections 60A(6) and (6A) to maintain their current effect by replacing the reference to "new information" with a reference to either or both "initial new information" and "later new information". It provides that either initial or later new information may be taken into consideration by the Secretary, or a delegate, in considering a remitted matter, treating that matter as if it were a fresh application for registration or a fresh application for a conformity assessment certificate.

Item 16
Item 16 extends the definition of ***authorised delegate*** to include a delegate of the Secretary exercising a power to decide whether to issue a conformity assessment certificate. This corrects an error in the existing provision.

Item 17 to 19
Items 17 and 18 insert definitions of ***initial new information*** and ***later new information*** in subsection 60A(8), and item 19 repeals the existing definition of ***new information***.

Initial new information means information that was in existence at the time the initial decision was made by the Secretary or the authorised delegate, and that information was not made available to the Secretary or the authorised delegate for the purpose of making that decision, and that information is relevant to that initial decision. Initial new information includes any opinions that are wholly or substantially based on such information (whether the opinions were formed before or after that initial decision was made).

Later new information is information that is supposed to have been provided to the Minister or delegate in her or his reconsideration of the initial decision as sought by the applicant for review under section 60 of the Act. Later new information is information that was in existence at the time the decision on reconsideration was made, was not made available to the Minister or authorised delegate for the purpose of making that decision and is relevant to the reconsideration decision. Later new information includes any opinions that are wholly or substantially based on such information (whether the opinions were formed before or after that reconsideration decision was made).

Item 20
Subitem (1) provides that the amendment made by item 3, requiring that a request for the imposition of new conditions under section 28 be accompanied by a prescribed fee, applies in relation to requests made on or after the commencement of that item (i.e. the day after Royal Assent).

Subitem (2) provides that the amendments made by items 4 and 5 above (relating to paragraph 42DL(1)(f)) apply to advertisements published or broadcast on or after the commencement of those items (i.e. the day after Royal Assent).

Subitem (3) provides that amendments made by items 8 to 15 and 17 to 19 (relating to 60A) apply in relation to requests made to the Minister under section 60 of the Act to reconsider initial decisions made on or after the commencement of those items (i.e. the day after Royal Assent), regardless of whether the initial decisions were made before, on or after the commencement of those items.

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2009

NOTES ON CLAUSES

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Bill, once enacted, as the *Therapeutic Goods (Charges) Amendment Act 2009*.

Clause 2: Commencement

This clause provides that the Bill commences on Royal Assent and that the various Schedules commence as set out in the table.

Schedule 1 will commence at the same time as Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2009* commences. This is to ensure that annual charges relating to the inclusion of biologicals as separate therapeutic goods in the Australian Register of Therapeutic Goods (the Register) can be levied from the commencement of provisions that enable their inclusion in the Register.

Clause 3: Schedules

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the relevant Schedule, and any other item in a Schedule to this Bill has effect in the way set out in the provision. The Bill makes amendments to the *Therapeutic Goods (Charges) Act 1989* (the Act) and includes application and transitional provisions.

SCHEDULE 1 – Amendments
This Schedule provides for the Charges Act to extend to cover biologicals included in the Register under Part 3-2A of the *Therapeutic Goods Act 1989* (the TG Act) as proposed to be inserted by the Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009.

It also provides that where a registered or listed good (under Part 3-2 of the Act) or a biological (under Part 3-2A of the Act, to be inserted by the Therapeutic Goods Amendment (2009 Measures No.3) Bill 2009) is suspended from the Register under the TG Act, that good can continue to be taken to be included in the Register for the purposes of the Charges Act.

This is to ensure that annual charges remain payable in respect of therapeutic goods that are suspended from the Register. This is necessary because suspension is temporary (not more than six months, unless it is extended) and does not result in a reduction to the usual regulatory work required to be undertaken by the Therapeutic Goods Administration (TGA) in relation to the good.

Items 1 and 2
These items amend section 3 to clarify the application of the Charges Act to therapeutic goods suspended under Part 3-2 or Part 3-2A of the TG Act and to amend the wording at subsection (2).

Item 1 inserts new subsections 3(1A) and (1B).

New subsection (1A) provides that where a registered or listed therapeutic good is suspended under Part 3-2 (section 29D) of the TG Act, then the goods are to be taken to be included in the Register under that Part for the purposes of the Charges Act.

New subsection (1B) provides that where a biological is suspended under Part 3-2A (section 32FA) of the TG Act (to be inserted by the Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009), then the biological is to be taken to be included in the Register under that Part for the purposes of the Charges Act.

Item 2 amends the wording at subsection 3(2) by removing the words ‘However, for’ and replacing these with the word ‘For’ to align the wording of that subsection with the wording of new subsections (1A) and (1B).

Items 3 and 4
These items amend section 4 which deals with the imposition of annual charges in relation to goods included in the Register under the TG Act.

Item 3 inserts a new subsection (1AA) after subsection (1A). This new subsection provides that an annual charge of a particular amount that is prescribed in the Regulations is payable in respect of the inclusion of a biological in the Register and that inclusion is in force at any time during the financial year.

The annual charge prescribed in the Regulations is payable in relation to a biological when that inclusion takes effect or is in force at any time during a financial year.
For example, if a biological is included in the Register under Part 3-2A of the TG Act on 25 June 2010, then an annual charge is payable in relation to that included biological for the financial year 2009-10, and an annual charge will also be payable for the next financial year

2010-2011, assuming the inclusion is in force at any time during that latter financial year. If the same biological is cancelled from the Register on 25 August 2010, annual charges are still payable for the financial year 2010-2011 as the relevant biological was included in the Register under Part 3-2A of the TG Act and was in force from 1 July to 24 August 2010.

The new subsection reflects the existing provisions in the Charges Act relating to registered or listed therapeutic goods (subsection (1)) and kinds of medical devices included in the Register (subsection (1A)).

Annual charges that remain unpaid at the end of the period of 28 days after they are due may be recovered by the Commonwealth as a debt due to the Commonwealth (refer to Schedule 5 of the Therapeutic Goods Amendment (2009 Measures No.3) Bill 2009)

Item 4 inserts a new subsection (4A) after subsection (4). This new subsection relates to the inclusion of biologicals in the Register and reflects the existing provisions relating to registered and listed therapeutic goods (subsections (3) and (4)) and medical devices (subsection (5)). The effect of the provision is that where biologicals are included in the Register in the exercise of a function or power conferred on the Secretary by a corresponding State law, annual charges apply as if the biological had been included in the Register under Part 3-2A of the TG Act.