EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 31

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2011 (No. 1)
Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 1)

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2011 (No. 1)

Subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The object of the Act is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia.

The object of the *Therapeutic Goods (Charges) Act 1989* (the Charges Act) is to allow the imposition of an annual charge on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods.

Section 4 of the Charges Act provides that annual charges of such amounts as are prescribed are payable in respect of entries of therapeutic goods in the Register and manufacturing licences. Subsection 5(1) of the Charges Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing amounts of charges.

The Therapeutic Goods Administration (the TGA) is responsible for administering the Act and the Charges Act.

The purpose of the Regulations is to implement details of the new regulatory framework for biologicals (a therapeutic good that comprises, contains or is derived from human cells or tissues) that are required to be prescribed under the provisions in Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No.3) Act 2010* (the Amendment Act), which will commence on 31 May 2011.

Specifically, the Regulations amend:

(a) the *Therapeutic Goods Regulations 1990* (the TG Regulations) to prescribe details of the regulatory framework that are required to be set out in the TG Regulations, to amend relevant provisions to include biologicals or exclude biologicals from the scope of those provisions, to make consequential changes and to provide for minor or technical amendments;
(b) the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to clarify that systems or procedure packs (which are regulated as medical devices under

the Act) may include one or more biologicals and to make other consequential changes; and

(c) the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) to prescribe annual charges that apply to biologicals.

The implementation of the details of the new regulatory framework for biologicals as set out in the Regulations support the regulation of biologicals as distinct therapeutic goods, and ensure that the level of regulation applied to biologicals is commensurate with the risk posed by the particular product by prescribing four risk based classes of biologicals.

The Regulations amend the TG Regulations to set out a number of requirements that be specific to biologicals, such as prescribing classes of biologicals, and specifying periods of time within which information relating to the adverse effects of biologicals must be given to the Secretary to the Department of Health and Ageing (the Secretary).

The Regulations also amend the TG Regulations to provide that relevant existing requirements that currently apply to medicines and which are appropriate and relevant in relation to biologicals, also apply to, or are replicated in relation to, biologicals. Examples of such measures include requirements relating to the transfer of goods (other than medical devices) within the Register, requirements relating to the disposal of unused emergency biologicals. The Regulations also prescribe applicable fees set out in Schedule 9A.

As the TGA recovers the full cost of its regulatory activities within the scope of the Act, there will be regulatory costs for sponsors of biologicals associated with the implementation of the new biological framework. Accordingly, the Regulations amend the TG Regulations to set out fees (such as evaluation fees) for biologicals, and amend the Charges Regulations to prescribe annual charges applicable to biologicals.

Details of the amendments to the TG Regulations are set out in Attachment A, details of the amendments to the MD Regulations are set out in Attachment B, and details of the amendments to the Charges Regulations are set out in Attachment C.

Neither of the Acts specify any conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are legislative instruments for the purposes of the *Legislative Instruments Act 2003.*

The Regulations commence on 31 May 2011, at the same time as the provisions set out in Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No.3) Act 2010*.

Consultation

The TGA undertook a public consultation on the Regulations from 22 October 2010 to 3 December 2010. The consultation included publishing a consultation paper on amendments to the TG Regulations to implement the biologicals framework, and inviting submissions in relation to that consultation paper. The TGA also held discussion forums in major capital cities in Australia during that period, where stakeholders were given the opportunity to ask questions regarding any issues relating to the biologicals framework.

A total of 151 stakeholders attended these sessions, and 30 written submissions were received by the TGA from public and private organisations. These submissions, as well as the consultation paper and an update to that consultation paper that was provided to stakeholders before and during the discussion forums, are available on the TGA's internet site (www.tga.gov.au).

Key issues of common concern raised by stakeholders in their submissions related to:

- a need for clarification regarding definitions of the classes of biologicals;
- a need for clarification of the definition of *minimal manipulation* (an important concept in the definitions of Classes 2, 3 and 4 biologicals), and whether specific processes may be included within that definition;
- requirements for exemptions from certain regulatory requirements for biologicals used in clinical trials; and
- a need for clarification of the responsibilities of medical practitioners in relation to the exemption of biologicals from certain regulatory requirements and in relation to the exceptional release of biologicals in specified circumstances.

The Regulations have been revised to take into account the concerns and submissions of stakeholders, where appropriate, particularly in relation to the issues noted above. The TGA is preparing a question and answer document which will address the main issues raised by stakeholders during the consultation. This document is expected to be included on the TGA's website in February 2011.

ATTACHMENT A

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2011 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provides that the name of the Regulations is the *Therapeutic Goods Amendment Regulations 2011 (No. 1)*.

Regulation 2 - Commencement
This regulation provides that the Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010* which will be on 31 May 2011.

Regulation 3 – Amendment of the *Therapeutic Goods Regulations 1990*
This regulation provides that Schedule 1 to the Regulations amends the *Therapeutic Goods Regulations 1990* (the TG Regulations).

Schedule 1 Amendments

Item [1] – Regulation 2, after definition of CHCA
This item inserts new definitions for the four classes of biologicals that are prescribed for the purposes of the biologicals regulatory framework (refer to new section 32AA of the Act).

It is intended that Class 1 biologicals, which are defined as those mentioned in new Schedule 16 to the TG Regulations, cover low risk biologicals where there is a high degree of medical oversight involved in their manufacture, as this level of supervision significantly reduces the risk to the patient.

On implementation of the framework there will not be any Class 1 biologicals mentioned in Schedule 16. The original intent had been for the biologicals framework to include solid organs for direct transfer and un-manipulated reproductive tissues. The Australian Health Minister's Council (AHMC) subsequently recommended that further consultation should take place with the affected sectors and that these cells and tissues should not be captured by the biologicals framework at this stage. Similarly, haematopoietic progenitor cells (HPCs) have not been included subject to further consultation with the sector. Fresh viable human organs or parts of human organs are currently not regulated as therapeutic goods under the Act (refer to the Therapeutic Goods (Excluded Goods) Order No. 1 of 2008).

However, the provision for Class 1 biologicals has been retained as part of the framework so that any or all of the above products may be included in the framework in the future if the Australian Government decides this is necessary and appropriate.

Class 2 biologicals are intended to be low risk biologicals that have been processed using only one or more of the actions of minimal manipulation (refer to item [5]) and which are for homologous use (meaning, the repair, reconstruction, replacement or supplementation of a recipient's cells or tissues with a biological that performs the same basic function in the recipient as in the donor (item [4] refers)). A class 2 biological also includes those mentioned in Schedule 16 to the TG Regulations, although noting that there will be no class 2 biological mentioned in Schedule 16 to the TG Regulations on the commencement of these Regulations.

Class 3 biologicals are biologicals that are processed using a method or methods, in addition to any actions of minimal manipulation (item [5] refers) and in a way that does not change an inherent biochemical, physiological or immunological property of the biological, or a biological mentioned in Schedule 16 as a Class 3 biological. Although noting that there not be class 3 biological mentioned in Schedule 16 to the TG Regulations on the commencement of these Regulations.

Class 4 biologicals are biologicals that are processed using a method or methods, in addition to any actions of minimal manipulation (item [5] refers) and in a way that does change an inherent biochemical, physiological or immunological property, or a biological mentioned in Schedule 16 as a Class 4 biological (noting, however, that there will be no Class 4 biological mentioned in Schedule 16 to the TG Regulations on the commencement of these Regulations). Class 4 biologicals are biologicals with the greatest risks associated with their use.

Classes 3 and 4 biologicals may include biologicals that are for non homologous use and the highest risk class, Class 4 biologicals, will have undergone substantial manipulation to alter a biological property. Class 3 biologicals include demineralised bone, cultured fibroblasts for skin repair or chondrocytes for cartilage repair, and Class 4 biologicals include genetically modified cells.

Items [2] and [3] – Regulation 2, definition of *designated therapeutic goods*, paragraph (c) and Regulation 2, definition of *designated therapeutic goods*, after paragraph (c)
Item [2] introduces a formatting change to paragraph (c) of the definition of designated therapeutic goods in regulation 2 of the TG Regulations, as a consequence of the amendment to this definition. Item [3] adds a new paragraph (d) referring to biologicals to the definition of *designated therapeutic goods*, thus excluding biologicals from being *designated therapeutic goods*. The effect of this amendment is to exclude biologicals being advertised in specified media as provided for under Division 2 of Part 2 of the TG Regulations. Division 2 of Part 2 of the TG Regulations is not intended to apply to biologicals and new paragraph 42DL(1)(fa) of the Act, provides that it is an offence for a person to publish or broadcast an advertisement that contains a statement about a biological unless authorised or required to do so by a government or government authority.

Item [4] – Regulation 2, after definition of *homoeopathic preparation*
This item introduces a definition for *homologous use* in the TG Regulations, with the meaning of that term being the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with a biological that performs the same basic function or functions in the recipient as in the donor. The meaning of homologous use is important in particular in relation to the descriptions of the classes of biologicals (item [2] refers).

Item [5] – Regulation 2, after definition of *immediate family*
This item introduces a definition of *minimal manipulation* in the TG Regulations, with that term referring to a process involving any one of a number of specified actions, those being: centrifugation; trimming, cutting or milling; flushing or washing; refrigeration; freezing; freeze drying (in relation to structural tissues); using additives such cryopreservatives, anticoagulants and antimicrobial agents; irradiation for the purposes of bioburden reduction; and any other similar action to those specified actions.

The definition for minimal manipulation are used to determine whether a biological is suitable for inclusion in Class 2 (as opposed to Classes 3 or 4) and is based on the complexity of the manufacturing process to which the biological has been subjected. The intention is for the

definition of minimal manipulation to be restricted to procedures and processes that maintain/preserve cells and tissues in a fit state for use but do not change the inherent physical or biological properties of the cells and tissues.

Item [6] – Regulation 2, after definition of *NFAA*
This item introduces a definition for *nonconforming biological* in the TG Regulations, defining that term as meaning a biological that is included in the Register under Part 3-2A of the Act but that does not conform with an applicable standard or with an applicable manufacturing requirement under the Act. This definition is used in relation to the exceptional release provisions (see new regulations 33A, 33B and 33C at item [25]). Applicable standards are those set out in the definition of "standards" under the Act that includes a standard that is constituted by the matters specified in an order by the Minister under section 10 of the Act that is applicable to the biological.

Item [7] – Regulation 2, after definition of *tuberculocide*
This item introduces a definition for *unused emergency biological* in the TG Regulations, defining that term as meaning a biological to which section 32CG of the Act applies. Section 32CG of the Act, which will commence as part of the regulatory framework for biologicals on 31 May 2011, deals with the disposal of unused biologicals that have been the subject of an exemption under section 32CA (exempted from certain regulatory requirements in order to be stockpiled to create a preparedness for a possible future emergency or in order to be used in relation to an emergency that has occurred).

Item [8] – Regulation 10B
This item, for the purposes of paragraph 9A(4)(b) of the Act, substitute a new regulation 10B to the TG Regulations (which sets out requirements relating to the transfer of therapeutic goods from one part of the Register to another) and allow biologicals to be transferred within the Register. The new regulation 10B then set out requirements relating to the following transfers within the Register:

(1) from the Part of the Register for listed goods - to the part of the Register for registered goods or biologicals;
(2) from the Part of the Register for registered goods - to the Part of the Register for listed goods;
(3) from the Part of the Register for registered goods - to the Part of the Register for biologicals;
(4) from the Part of the Register for biological - to the Part of the Register for listed goods, registered goods or medical devices;
(5) from the Part of the Register for medical devices - to the Part of the Register for registered goods, listed goods; and
(6) from the Part of the Register for medical devices - to the Part of the Register for biologicals.

The circumstances set out above are covered by new subregulations 10B(1) to (6), in that order. The requirements relating to applications for the transfers of therapeutic goods in the Register involving biologicals are mandatory.

Subregulation 10B(7) specifies the period when an application under subregulations 10B(1), (3), (4) or (6) must be made. It is an offence if the relevant person does not make an application for the transfer of the biological within the prescribed period. Paragraph 10B(7)(a) provides that the period can be the period notified by the Secretary to a person in whose name the goods are entered in the Register and paragraph 10B(7)(b) provides that in any other case, the specified period for applications to be made is within 15 months after the day when the goods

became subject to inclusion in the part of the Register for registered goods or were specified by the Secretary to be a biological under subsection 32A(2) of the Act.

Subregulation 10B(8) provides that the offence set out in subregulation 10B(7) for failing to make an application within the prescribed period (which has a maximum penalty of 5 penalty units) is an offence of strict liability.

Subregulation 10B(9) specifies the kinds of matters that the Secretary must consider in determining a period of notice for paragraph 10B(7)(a).

Subregulation 10B(10) provides that it is not an offence for the sponsor of the goods to which subregulation (1), (3), (4) or (6) applies, to import, export, supply or manufacture the goods as listed goods, registered goods, medical devices included in the Register under Chapter 4 of the Act or biologicals included in the Register under Part 3-2A of the Act until the later of:

(a) the expiry of the time for making the application under subregulation 7; or
(b) if an application for the transfer of an entry in the Register is made-when the application is determined.

Subregulation 10B(11) provides that any application for the transfer of an entry in the Register under regulation 10B is taken to be an application for registration, listing or inclusion of the goods.

However, this regulation does not apply to those circumstances set out in section 32DN of the Act in relation to biologicals.

Item [9] – After Division 2C.2

This item inserts a new Division 2C.3 – Biologicals included in the Register into the TG Regulations that apply to biologicals and which largely mirror the existing requirements set out in Division 2C.1 of the TG Regulations for registered and listed goods by making provisions for the inclusion of biologicals in the Register under Part 3-2A. Division 2C.3 includes new regulations 10G (Goods to be included in the part of the Register for biologicals), 10H (Change of person for whom a biological is included in the Register under Part 3-2A of the Act), 10I (Re-assignment of biological numbers) and 10J (Notice of reassignment of biological numbers).

Regulation 10G – Goods to be included in the part of the Register for biologicals.

The effect of this regulation requires, for the purposes of paragraph 9A(4)(a) of the Act, that therapeutic goods, and classes of therapeutic goods, that are biologicals and that are included in the Register under Part 3-2A of the Act are to be included in the part of the Register for biologicals.

Regulation 10H – Change in person in relation to whom a biological is included in the Register

Regulation 10H aligns with current regulation 10A and identifies various circumstances in which the person in relation to whom a biological is included in the Register is taken to have changed, such as for example, where the person in relation to whom a biological is included in the Register under Part 3-2A of the Act dies, or becomes bankrupt or, where the person is a body corporate, is wound up. Regulation 10H is intended to mirror for biologicals, the requirements of existing regulation 10A, which sets out circumstances in which the person in relation to whom registered or listed therapeutic goods is taken to have changed.

Regulation 10I – Re-assignment of biological numbers
This regulation, for the purposes of new paragraph 9A(4)(ca) of the Act allows a person in whose name a biological is included in the Register under Part 3-2A to apply for, and be assigned, a different biological number (being, essentially, a number that is unique to the biological, assigned by the Secretary either under certain provisions of the Act or following an application for reassignment under this regulation (refer to the definition of biological number at subsection 3(1) of the Act). The application must be made in writing and must include sufficient information to allow the application to be properly considered.

Regulation 10J – Notice of re-assignment of biological numbers.
This regulation requires the Secretary to give notice in writing to a person in whose name a biological is included under Part 3-2A of the Act, if a new biological number is assigned to that biological under regulation 10I.

Item [10] – Part 3, heading
This amendment substitutes for the current heading of Part 3 of the TG Regulations a new title "*Registration, inclusion, listing and exemption of therapeutic goods*". The only effect of this change is to include the reference to "inclusion" in that title. This amendment is intended to reflect that, following commencement of the Regulations, Part 3 of the TG Regulations also applies to biologicals and that biologicals are '*included*' in the Register under Part 3-2A of the Act (as opposed to being registered or listed).

Item [11] – Regulation 12
This item substitutes new regulations 11A and 12 for the current regulation 12 of the TG Regulations.

New regulation 11A, for the purposes of new section 32AB of the Act, specifies the criteria that distinguishes a biological from other biologicals for the purposes of identifying whether a new application for inclusion in the Register and a new Register entry is required. Class 1 and 2 biologicals are deemed to be separate and distinct from other biologicals if they have different applicable standards, intended clinical uses or principal manufacturers. Class 3 and 4 biologicals are deemed to be separate and distinct from other biologicals if they have different product names, dosage forms, formulations or compositions, therapeutic indications, types of container (disregarding container size) or principal manufacturers. Subregulation 11A(2) defines *principal manufacturer* for the purpose of regulation 11A as the person who carries out the total manufacture of the biological and if more than one manufacturer is involved, the person who takes overall responsibility for the manufacture of the biological which includes releasing for supply.

Item [11] expands the coverage of existing regulation 12. Regulation 12 currently prescribes the therapeutic goods or classes of therapeutic goods that are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F), for the purposes of subsection 18(1) of the Act. The therapeutic goods exempt from these requirements are set out in Schedules 5 and 5A to the TG Regulations.

New regulation 12 prescribes biologicals and other therapeutic goods (that are not medical devices) that are exempt from the requirements of Part 3-2A in relation to the inclusion of biologicals in the Register and in relation to registration or listing of therapeutic goods under Part 3-2 of the Act. The exemption from the requirement to include biologicals in the Register are set out in subsection 32CA(2), which provides that the regulations may exempt specified biologicals from the operation of Division 4 of Part 3-2A of the Act.

Subregulation 12(1) provides that for the purposes of subsection 18(1) and 32CA(2) of the Act, the therapeutic goods or classes of therapeutic goods mentioned in Schedule 5 are exempt from the operation of Part 3-2 (except for specified sections under Part 3-2) and Division 4 of Part 3-2A. Any therapeutic good or class of therapeutic good listed in Schedule 5 is not required to be registered, listed or included in the Register under Part 3-2A.

Subregulation 12(2) provides that for the purposes of subsection 18(1) and 32CA(2) of the Act, the therapeutic goods or classes of therapeutic goods mentioned in Schedule 5A are exempt from the operation of Part 3-2 (except for specified sections under Part 3-2) and Division 4 of Part 3-2A. However, these exemptions are subject to compliance with the conditions mentioned in column 3 of an item in Schedule 5A. The exemption therefore is subject to the conditions being met, and that if any of those conditions are not met, the therapeutic good or the class of therapeutic good mentioned in Schedule 5A is no longer exempt from the operation of Part 3-2 and Division 4 of Part 3-2A (subregulation 12(3)).

Subregulation 12(4) provides that if the therapeutic goods to which regulation 12 applies cease to be exempt goods, and the sponsor of the goods applied for registration, listing or inclusion of the goods in the Register before the exemption ceases, the exemption from the requirements set out in regulation 12 is taken to apply to the goods until the application for registration, listing or inclusion of the biological in the Register is determined.

Item [12] – Regulation 12A, heading

This item substitutes the current heading for regulation 12A, which specifies medicines that are exempt from the requirement to be included in the Register for the purposes of subsection 18(1) of the Act in life-threatening cases, with a new heading "*Unapproved medicines and biologicals – exemption in life-threatening cases*", as it amends regulation 12A to also include the exemption of biologicals in such circumstances (items [13] and [14] refer).

Items [13] and [14] – After subregulation 12A(1), and Subregulation 12A(2)

Item [13] expands the requirements of the existing regulation 12A, which specifies medicines that are exempt from the requirement to be included in the Register for the purposes of subsection 18(1) of the Act in life-threatening cases, to include within its scope biologicals for the purposes of subsection 32CA(2) of the Act. This has the effect of exempting a specified biological from the requirement to be included in the Register under Part 3-2A if that particular biological is used in life-threatening cases in accordance with the conditions set out at existing subregulation 12A(2) of the TG Regulations.

These conditions are: that the intended recipient is seriously ill, that the recipient or their guardian has given their informed consent to the use of the biological and that the medical practitioner who is giving the product or directing the giving of the biological to the recipient has signed a statement in the form approved by the Secretary and the biological is dispensed on the prescription of a medical practitioner in accordance with good medical practice.

Item [14] adds after each reference to "medicine" in subregulation 12A(2) of the TG Regulations "or biological" to support this amendment.

Item [15] –Regulation 12AAB, heading

This item substitutes the current heading of regulation 12AAB of the TG Regulations (which refers to "Disposal of unused emergency goods") with the new heading "*Disposal of unused emergency goods and unused emergency biologicals*" in order to make it clear that the

requirements for the disposal of unused emergency goods that are set out in regulation 12AAB also apply to biologicals (item [16] refers].

Item [16] – Subregulation 12AAB(1)
This item substitutes the existing subregulation 12AAB(1) of the TG Regulations with a new subregulation 12AAB(1). The existing subregulation 12AAB(1) provides that for the purposes of subsection 30G(2) of the Act that Schedule 5B to the TG Regulations sets out requirements relating to the disposal of unused emergency goods. The new subregulation 12AAB(1) retains this reference and expand the scope of the existing subregulation 12AAB(1) to apply to an unused emergency biological for the purposes of new subsection 32CG(2) of the Act. Unused emergency biological (item [7] refers) and unused emergency good are defined in regulation 2.

Item [17] – After subregulation 12AAB(2)
This item adds a new subregulation 12AAB(3) to the TG Regulations in order to essentially mirror the requirements of existing subregulation 12AAB(2) of the TG Regulations in relation to biologicals. The effect of this change is to make it clear that subregulation 12AAB(1) and Schedule 5B are not to be taken to prevent a disposal of unused emergency biologicals if any of the circumstances listed at subparagraphs 12AAB(3)(a)(i) to (iv) apply (such as if the biological has been included in the Register) and the disposal is in accordance with other relevant provisions of the Act and the TG Regulations that are relevant to the biological.

Item [18] – Regulation 12AA
Regulation 12AA to the TG Regulations sets out, for the purposes of subsection 19(2) of the Act, information that the Secretary may require from persons who apply for an approval to import into, export from or supply in, Australia, therapeutic goods that are not registered, listed or exempted from the requirement to be included in the Register and that are to be used solely for experimental purposes in humans. This item omits some text from regulation 12AA of the TG Regulations and insert new wording, with the effect that the Secretary could also seek the kinds of information listed in regulation 12AA in relation to biologicals that are the subject of an application under subsection 32CK(1) of the Act for use solely for experimental purposes in humans (described in paragraph 32CK(1)(e)).

This information includes information relating to the names and members of the relevant ethics committee that gave approval to the trial and who be involved in monitoring the conduct of each trial, the details of various persons involved in clinical trials and whether or not any conditions specified by the ethics committee have been met.

Item [19] – Subregulation 12AB(1)
This item substitutes a reference to "subsection 19(1A)" with "subsections 19(1A) and 32CK(8)". This has the effect of ensuring that the importation of biologicals for use solely for experimental uses in humans (clinical trials) is required to meet the same conditions that apply in relation to an approval for the importation of other therapeutic goods for the same purpose under Chapter 3 of the Act. This includes requirements relating to good clinical practice and the provision of information about the conduct and approval of a clinical trial when requested to do so by an authorised officer.

Item [20] – Regulation 12AD
This item substitutes a reference to "subsection 19(4A)" with "subsections 19(4A) and 32CL(1)". This change has the effect of ensuring that the conditions that currently apply in relation to the use of therapeutic goods (other than medical devices) for experimental purposes also apply to biologicals. This includes a requirement for good clinical practice and

compliance with the ethical standards set out in the National Statement on Ethical Conduct in Research Involving Humans.

Item [21] – Regulation 12B, heading
This item substitutes the current heading for regulation 12B (which refers to "Exemptions for special and experimental uses") to "*Exemptions for special and experimental uses – medicines*" in order to specifically exclude biologicals, which are covered by a new regulation 12C (detailed in item [22]).

Item [22] – After regulation 12B
This item introduces a new regulation 12C in the TG Regulations, titled "Exemptions for special and experimental uses – biologicals". New regulation 12C, for the purposes of new paragraph 32CM(4)(a) and new subsection 32CM(5) of the Act have the effect of enabling the Secretary to authorise specified medical practitioners to supply specified biologicals to recipients who are suffering life-threatening or serious illnesses.

Subsection 32CM(4) of the Act, to commence on 31 May 2011, provides that an authority of the Secretary for a medical practitioner to supply a biological under subsection 32CM(1) of the Act may only be given to a medical practitioner included in a class of medical practitioners prescribed by the regulations (paragraph 32CM(4)(a)), or to a medical practitioner who has the approval of an ethics committee to supply the biological (paragraph 32CM(4)(b)).

Subregulation 12C(1), for the purposes of paragraph 32CM(4)(a) of the Act, prescribes medical practitioners engaged in clinical practice in or outside a hospital, as the class of medical practitioners that can be authorised by the Secretary under subsection 32CM(1) to supply specified biologicals for use in the treatment of humans to specified recipients .

Subregulation 12C(2) has the effect of dis-applying the requirement in paragraph 32CM(4)(b) of the Act for a medical practitioner to have the approval of an ethics committee to supply a specified biological in order to be the subject of an authorisation from the Secretary under subsection 32CM(1), in specified circumstances. Those circumstances are where the medical practitioner is engaged in clinical practice outside a hospital and has demonstrated that, for the supply of the biological, he or she does not have access to an ethics committee but has received an endorsement to supply the biological from a specialist college with established expertise relevant to the use of the biological.

Subregulation 12C(3) has the effect of prescribing, for the purposes of subsection 32CM(5) of the Act, persons suffering from a life-threatening or serious illness or condition as the class of recipients to whom the Secretary may authorise biologicals to be supplied under subsection 32CM(1) of the Act.

Subregulation 12C(4) prescribes the circumstances in which a biological may be supplied under an authority under subsection 32CM(1) (for the purposes of subsection 32CM(6)). These circumstances are that the supplier of the biological complies with any treatment directions mentioned in the authority for the supply of the biological.

Item [23] – After regulation 16AA
This item inserts a new regulation 16AB that species timeframes within which a person in relation to whom a biological is included in the Register and who is aware of specified information relating to the adverse effects of biologicals (refer to subsection 32DQ(3)) must provide that information to the Secretary. New subsections 32DQ(1) and (2) of the Act set out

a criminal offence and civil penalty provision relating to the failure by such a person to provide the required information to the Secretary within the period specified in the regulations. The kinds of information that are required to be provided are described in new subsection 32DQ(3) of the Act, and include information that indicates that the use of a biological in accordance with the recommendations for its use may have an unintended harmful effect.

The specified periods are as follows:

(a) within 48 hours after the person becomes aware of the event or occurrence if the information relates to an event or occurrence that represents a serious threat to public health;
(b) within 10 days after the person becomes aware of the event or occurrence if the information relates to an event or occurrence that lead to the death or serious deterioration in the state of health of a patient, a user of the biological or another person;
(c) within 30 days after the person first becomes aware of the event or occurrence if the information relates to an event or occurrence that , if it occurred again, might lead to death, or serious deterioration in the state of health, of a patient, a user of the biological or another person.

Item [24] – Part 3A, after Division 2

This item inserts a new Division 3 in Part 3A of the TG Regulations, which applies to the following:

- applications for the inclusion of a biological (other than a class 1 biological)in the Register under Part 3-2A and the evaluation of biologicals that are the subject of those applications under section 32DE of the Act; and
- an application for variation of an entry in the Register; and
- evaluation of a new substance or a new excipient for use in biologicals.

New Division 3 includes new regulations 16GB (Notification of acceptance or rejection of application), 16GC (Periods within which certain evaluations must be made), 16GD (Periods within which certain applications must be decided), 16GE (Failure to decide an application within specified time) and 16GF (Evaluation, other than evaluation under subsection 9D(3A) or (3AA) or section 32DD of the Act). These new regulations mirror the requirements set out in existing regulations 16B, 16C, 16D, 16E and 16GA, to apply to Class 2, 3 and 4 biologicals.

The effect of these new provisions is to ensure that biologicals that require pre-market evaluation are subject to similar requirements to those currently applying in relation to prescription medicines, including in relation to the following:

(a) requiring the Secretary to notify an applicant in writing within 40 days (regulation 16GB) whether the application has been accepted for evaluation or rejected. This regulation only applies to the evaluation of applications under section 32DD (inclusion of a Class 2, 3, or 4 biological in the Register) of the Act and applications under subsection 9D(3A) or (3AA) of the Act for a variation in the entry in the Register;
(b) requiring an evaluation of a Class 2, 3 or 4 biological under section 32DE of the Act to be completed within 365 calendar days (regulation 16GC) after the Secretary sends a notification of the acceptance of the application for evaluation. This requirement aligns with timeframes for the evaluation of a prescription medicine in current sub-regulation 16C(3)(b);
(c) requiring the evaluation of an application for a variation to the entry of a Class 2, 3 or 4 biological in the Register to be completed within 365 calendar days (regulation

16GD) after the Secretary sends a notification to the applicant under regulation 16GB that indicates acceptance or rejection of the application . This aligns with the timeframes for the evaluation of a prescription medicine in current sub-regulation 16D(3)(b);

(d) specifying that failure to decide an application within the time mentioned in 16GD(2) does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury of any kind, that is caused by or arises of the failure (regulation 16GE);

(e) allowing the Department, at the request of a person and on payment by the person of the prescribed fee, to evaluate data submitted by the person, being data that relates either to a substance which is not an ingredient in a biological supplied in Australia but that may be an ingredient in a biological the subject of an application for inclusion in the Register and which is supplied in Australia if so included; or to a substance that is a new excipient in a biological, provided that the substance is not used as an ingredient in any other biological supplied in Australia at the time of inclusion in the Register under Part 3-2A of the Act (regulation 16GF). An evaluation under regulation 16GF may be made although there is no current application for variation of the entry in the Register under subsection 9D(3A) or (3AA) or an application for inclusion of a Class 2, 3 or 4 biological under section 32DD.

Item [25] – After Part 5

This item inserts a new Part 5A, including new regulations 3A, 33B and 33C after existing Part 5.

Part 5A – Exceptional release

Paragraphs 14(5A)(b), (9A)(b), (9A)(b), (13A)(b), 14A(1A)(b), section14A(2A) and paragraph 14A(3A)(b) of the Act provide for an exception applying to biologicals in relation to the requirement that therapeutic goods supplied, exported or imported into Australia must conform with applicable standards, unless those non-conforming goods are supplied, exported or imported into Australia with the consent in writing of the Secretary. This exception applies where a person supplies, exports or imports those biologicals after the circumstances prescribed by the regulations have occurred.

Regulations 33A, 33B and 33C specifies the exceptional circumstances where a nonconforming biological can be released by a sponsor for supply to a patient suffering from a serious condition and who is urgently in need of such a biological, subject to specified conditions, without contravening the specified offence and civil penalty provisions under sections 14 and 14A. A nonconforming biological is a biological that does not conform with standards that are applicable to the goods or does not conform to the applicable manufacturing requirements under the Act (item [6] refers).

For example, a patient who has Hepatitis C may require a biological urgently and the only available biological is not able to have the necessary testing for the virus completed before the patient needs it. It is possible that under normal circumstances the presence of the virus, (where the biological could not be treated to remove it) renders the biological nonconforming for use; however, in this circumstance a treating doctor may assess that the nonconforming biological to be suitable for the treatment of that particular patient. The biological is entered in the Register and has undergone the necessary assessment required prior to its entry in the Register under Part 3-2A. The release of this non-conforming biological in specified circumstances subject to conditions is suitably termed as exceptional release under which non-conforming biologicals may be imported, exported or supplied.

Regulation 33A prescribes the circumstances under which a biological that does not meet all of the prescribed standards or manufacturing requirements may still be imported, exported or supplied in Australia. These prescribed circumstances must be all satisfied for the exceptions under the relevant sections 14 and 14A to apply. These circumstances are:

(a) the patient has been clinically assessed by the treating medical practitioner to require the biological urgently to treat a serious condition; and
(b) a biological that is included in the Register under Part 3-2A of the Act and conforms with the applicable manufacturing requirements and standards, is not available, or not available within the time necessary for treatment to occur; and
(c) a nonconforming biological is available that is included in the Register but it does not conform with the relevant standards specified under the Act and/or the relevant manufacturing principles as specified under section 36 of the Act; and
(d) no other treatment option is suitable for the patient; and
(e) the nonconforming biological is assessed as the most suitable treatment; and
(f) the nonconforming biological is to be used only for the treatment of one patient.

Subsection 15AB(1) of the Act provides that the regulations for the purposes of paragraphs 14(9A)(b) and 14A(2A)(b) (relating to exceptions applying to the supply of biologicals that do not conform with applicable standards in relation to the biologicals) may also prescribe conditions that apply in relation to the supply of biologicals that occurs after the circumstances prescribed for the purposes of those paragraphs occur.

Subregulation 33B(1) prescribes the following conditions that must be all met for the supply of nonconforming biologicals for the purposes of subsection 15AB(1) of the Act:

(a) all the circumstances mentioned in regulation 33A have occurred; and
(b) the sponsor of the non-conforming biological mentioned in paragraph 33A(c) was provided a copy of a written statement about the following from the patients' treating medical practitioner:
    (i) the proposal to use the nonconforming biological;
    (ii) that the patient or guardian has been told about the likely risks and benefits from the use of the biological;
(c) why the biological is nonconforming with standards applicable to the goods or was not manufactured in accordance with relevant manufacturing principles under section 36 of the Act; and
(d) the medical or scientific director of the sponsor's facility from which the supply is to occur must have given written approval for the release of the biological; and before the biological is used, the patient or the patient's guardian must give written informed consent or the treating medical practitioner must give written statement of the reasons that consent cannot be given; and
(e) that consent and the approval must be placed on the patient's medical records and a copy given to the treating doctor.

Subregulation 33B(2) require the sponsor to give to the Secretary within 28 days of the release of the nonconforming biological, a notification of use of the nonconforming biological using a form approved by the Secretary; a copy of the written statement given by the treating medical practitioner to the sponsor, the written approval of the medical or scientific director for the release of the non-conforming biological, and the written informed consent of the patient or the patients guardian or if applicable, the statement of the reason why a consent cannot be given.

Subregulation 33B(3) requires the Secretary to give to the sponsor of the non-conforming biological a written acknowledgement of the receipt of the notification within 28 days of receiving the notification and the receipt of further information requested by the Secretary.

Regulation 33C requires the sponsor to give the Secretary the following:

(a) report within 6 months of the release of the non-conforming biological from a cell or tissue bank providing the following information: date of release; product identification details, name and address of transplant centre or medical practitioner to whom the biological was released; patient initials, date of birth and gender, any adverse events relating to the use of the nonconforming biological; and
(b) information about the supply of the nonconforming biological and the circumstances surrounding the supply within 14 days after the request is given by the Secretary, that includes the following: the decision making process leading to the supply of the non-conforming biological and any adverse events related to the supply.

Item [26] – After subparagraph 34A(1)(a)(vi)

This item inserts a new subparagraph 34(1)(a)(vii) to subregulation 34A(1) of the TG Regulations, with the effect that the Therapeutic Goods Committee (which advises and makes recommendations to the Minister on the matters relating to therapeutic goods that are specified at paragraph 34A(1)(a), and advises and makes recommendations to the Minister or the Secretary on matters referred to the committee by the Minister or the Secretary) could advise and make recommendations to the Minister on matters relating to standards for biologicals.

Item [27] – Part 6, after Division 1E

This item inserts a new Division 1EA in Part 6 of the TG Regulations, to establish and set out the functions and membership of a new advisory committee, the Advisory Committee on Biologicals (the ACB). New Division 1EA encompasses new regulations 39C, which establishes the ACB, new regulation 39D, which specifies the functions of the ACB and new regulation 39E, which sets out requirements in relation to the membership of the ACB.

Under new regulation 39D, the ACB's functions are to advise and make recommendations to the Minister or the Secretary on the matters specified at paragraphs 39D(1)(a) – (e), including the inclusion of a biological in the Register (39D(1)(a)), the variation of an entry in the Register in relation to a biological (39D(1)(b)) and any other matter referred to the ACB by the Minister or the Secretary (39D(1)(e)).

Under new regulation 39E, the Minister could, in writing, appoint up to 12 persons to the ACB, being persons with expertise in at least one of the fields of expertise listed at paragraphs 39E(2)(a) to (j), including infectious diseases (39E(2)(a)), cellular therapies, including tissue engineering (39E(2)(d)) and organ and tissue transplantation (39E(2)(f)).

Item [28] – Regulation 40

It is important to note that the requirements of Division 1F of the TG Regulations, which deal with administrative matters such as the appointment of members of advisory committees, a leave of absence by the chair of an advisory committee and committee procedures, also applies in relation to the ACB. To make this clear, regulation 40 includes a reference to Division IEA – the Advisory Committee on Biologicals.

Item [29] – Part 7, Division 1, Subdivision 1, heading

This item substitutes the current heading of Part 7, Division 1, Subdivision 1 (which provides "Charges for registration, listing and inclusion of therapeutic goods, exemptions and licences")

with the new heading "*Charges for registration, listing and inclusion of medical devices and biologicals",* in order to make it clear that biologicals are also be covered in this Subdivision as a result of changes that are introduced by the regulations at items [30] to [32] below.

Items [30] and [31] – Regulation 43AAB, and Subregulations 43AAC(1) and 43AAE(1)
These items, respectively, substitute a new regulation 43AAB (the definition provisions) for the existing regulation 43AAB of the TG Regulations, and amend subregulations 43AAC(1) and 43AAE(1) to make it clear that references in those provisions to "therapeutic good" should not be taken to include biologicals.

The effect of these changes is to exclude biologicals from the application of Subdivision 2, Division 1 of Part 7 relating to the exemption from the liability to pay annual charges (listing, registration or inclusion of therapeutic goods in the Register) in the relevant financial year on the ground that for the applicable financial year the turnover of the particular good entered in the Register is of low value turnover. This is because a large number of biologicals meet the low value turnover provisions making cost recovery impossible for this sector.

It should be noted that in recognition of the fact that a significant proportion of biologicals manufacture is undertaken in public not-for-profit facilities, the Australian Government (through Australian Health Ministers' Advisory Council (AHMAC)) agreed to meet the direct regulatory costs of such facilities for the first three years following the implementation of the new regulatory framework for biologicals.

Item [32] – Subregulation 43AAG(5)
This item corrects an error at subregulation 43AAG(5) of the TG Regulations by replacing the word 'subregulaton' with 'subregulation'.

Item [33] – Subregulation 43(1)
This item substitutes a new subregulation 43(1) for the existing subregulation 43(1) of the TG Regulations, with the intention of expanding the scope of the subregulation to also reference new Schedule 9A which, under the Regulations, set out applicable fees applying to biologicals.

Item [34] – Subregulations 45(2) and (4)
This item substitutes the references to "Schedule 9" in each of subregulations 45(2) and (4) of the TG Regulations with references to "Schedules 9 and 9A". Subregulations 45(2) and (4) set out, respectively, the circumstances in which the Secretary may waive or reduce a prescribed evaluation fee in relation to certain matters. This has the effect of authorising the Secretary to reduce or waive evaluation fees where an applicant for inclusion of a biological in the Register makes more than one application and there is common data or the Secretary already has information relating to the goods enabling simultaneous evaluation of the goods or the evaluation procedure to be abridged. The TGA will develop business rules to provide further detail about the circumstances when waiver or reduction of fees may apply, as well as details on the level of fee reductions.

The Regulations do not amend subregulation 45(1) to allow biologicals to claim 70 per cent reduction in the evaluation fee, as it is believed that the majority of biologicals are able to comply with this provision. This is consistent with the 2006 AHMAC recommendation that "The costs of regulating are to be fully cost recovered from the regulated entities". It should be noted that in recognition of the fact that a significant proportion of biologicals manufacture is undertaken in public not-for-profit facilities, the Australian Government (through AHMAC)

agreed to meet the direct regulatory costs to such facilities for the first three years following the implementation of the new regulatory framework for biologicals.

Item [35] – Paragraph 45(4)(b)
This item introduces a formatting change to paragraph 45(4)(b) of the TG Regulations that is necessary in order to accommodate the addition of new paragraphs 45(4)(c) and (d) under item [36].

Item [36] – After paragraph 45(4)(b)
This item introduces new paragraphs 45(4)(c) and (d) in the TG Regulations, with the effect that the Secretary could waive or reduce an evaluation fee in relation to an application to include a biological in the Register or an application to vary an entry in the Register for a biological, if the Secretary has information relating to the goods that enable the evaluation procedure to be abridged.

Item [37] –Subregulation 45AA(1)
This item inserts a reference to "item 4, 5, 6, 10 or 11 in Schedule 9A" after the reference to "Schedule 9". Inclusion of these fee items in subregulation 45AA(1) means that an applicant for the inclusion of a class 2, 3 or 4 biologicals or an applicant for the variation of an entry of a class 3 or 4 biological included in the Register could apply for the payment of evaluation fee by instalment. The Secretary has, under subregulation 45AA(1), the discretion to allow the payment of these evaluation fees by instalment if the requirements of that provision are complied with.

Item [38] –Subparagraph 46(2)(a)(i)
Regulation 46 of the TG Regulations prescribes kinds of therapeutic goods information which the Secretary may release to a person, on application by the person, for the purposes of subsection 61(6) of the Act. This item amends subparagraph 46(2)(a)(i) which deals with the release in such circumstances of information relating to whether goods are included in the Register, to allow for the release of the biological number of a biological which is the subject of a request under subsection 61(6) of the Act.

Items [39] and [40] – Paragraph 46(2)(e)
These items amend paragraph 46(2)(e) of the TG Regulations to include a reference to "or biological" after each reference in that paragraph to "medicine", with the effect that the Secretary could, under subsection 61(6) of the Act and paragraph 46(2)(e), release to a person, on application by that person, therapeutic goods information of a kind described in any one or more of subparagraphs 46(2)(e)(i) to (viii) in relation to a biological as well as in relation to a medicine.

Items [41] and [42] – Paragraph 46(2)(g) and After paragraph 46(2)(g)
Item [41] introduces a formatting change to paragraph 46(2)(g) of the TG Regulations (paragraph 46(2)(g) deals with the release of information under regulation 46 regarding whether goods are a designated orphan drug) that is necessary in order to accommodate the insertion of new paragraph 46(2)(h).

Item [42] introduces a new paragraph 46(2)(h), the effect of which is to permit the Secretary to release to a person under subsection 61(6) of the Act and new paragraph 46(2)(h) therapeutic goods information relating to which class of biological to which goods that are biologicals belong.

Item [43] – Regulation 47A, heading
This item substitute a new heading for the current heading of regulation 47A, with the effect that the new heading to regulation 47A refers to "*Delegation – powers under paragraphs 19(1)(a), 32CK(1)(d) and 41HB(1)(d) of the Act"*, in order to make it clear that, under the Regulations, regulation 47A (in addition to its existing scope) makes provision for the delegation by the Secretary of his or her powers in relation to specified biologicals under paragraph 32CK(1)(d) of the Act.

Item [44] – Subregulation 47A(1)
Amendments to subsection 57(3) of the Act that commence 31 May 2011 will permit the Secretary to, subject to the regulations and in such circumstances as are prescribed, delegate by signed instrument any or all of his or her powers under paragraph 32CK(1)(d) of the Act to grant approval for the import into, export from or supply in, Australia, of specified biologicals for use in the treatment of another person or for use solely for experimental purposes in humans, to a person who is registered in a State or internal Territory as a medical practitioner. Subsection 57(3) already provides for the Secretary to delegate to such persons his or her powers in respect of therapeutic goods (under paragraph 19(1)(a) of the Act) and medical devices or kinds of medical devices (under paragraph 41HB(1)(d) of the Act). Regulation 47A of the TG Regulations qualifies the powers of the Secretary to delegate his or her powers under subsection 57(3) and prescribes circumstances relating to such delegations, for the purposes of that provision.

This item substitutes a new subregulation 47A(1) for the existing subregulation 47A(1) of the TG Regulations. The new subregulation 47A(1) replicates the existing wording of subregulation 47A(1) but include references to paragraphs 41HB(1)(d) and 32CK(1)(d) of the Act.

Item [45] – Subregulation47A (4)
Item [45] makes an amendment to subregulation 47A(4) as a consequence of the amendment to subregulation 47A(1) (item [44] above). Subregulation 47A(4) currently requires that a delegation of the Secretary's powers under paragraph 19(1)(a) of the Act must describe the person or class of persons to be treated with the therapeutic goods to which the delegation relates. As item [44] amends subregulation 47A(1) of the TG Regulations to include references to paragraphs 32CK(1)(d) and 41HB(1)(d) of the Act, item [45] also amends subregulation 47A(4) to include reference to biologicals and medical devices.

Items [46] and [47] – Paragraph 47A(5)(b) and After paragraph 47A(5)(b)
Item [46] introduces a formatting change to paragraph 47A(5) of the TG Regulations to facilitate the amendment set out in item [47].

Item [47] amends paragraph 47A(5)(b) of the TG Regulations, in order to make it clear that a delegation may be made by the Secretary under subsection 57(3) of the Act for the purpose of allowing a delegate to grant an approval in relation to a particular item or class of therapeutic goods, a particular biological or class of biologicals or a particular medical device or kind of medical device.

Item [48] – Paragraphs 47A(6)(a) and (b)
This item substitutes the current paragraphs 47A(6)(a) and (b) with new paragraphs (a) and (b) as a consequence of the amendment to subregulation 47A(1) to include reference to the delegation of the Secretary's powers under paragraph 32CK(1)(d) and 41HB(1)(d) of the Act. Item [48] amends paragraphs 47A(6)(a) and (b) to include reference biologicals and medical

devices, and include references to paragraphs 32CK(1)(d) and 41HB(1) (d) of the Act. Subregulation 47A(6) specifies the requirements that must be satisfied for a delegate to grant an approval under a delegation as defined in subregulation 47A(1).

Item [49] – Regulation 47B, heading
This amendment substitutes the current heading for Regulation 47B to "*Provision of information concerning medicines, biologicals and medical devices*" in order to make it clear that regulation 47B also applies to biologicals.

Items [50], [51], [52], [53] and [54] – Paragraph 47B(1)(b), Paragraph 47B(3)(a), Paragraph 47B(3)(b), Subregulation 47B(4) and Subparagraphs 47B(5)(b)(i) to (iv)
Items [50] to [54] include consequential changes required in relation to regulation 47B to include biologicals, persons authorised under subsection 32CM(1) and delegates under subsection 57(3) of the Act relating to biological (item [44] above refers). Regulation 47B requires persons to whom the Secretary has delegated his or her powers under subsection 57(3) of the Act, persons authorised by the Secretary under subsections 19(5) or 41HC(1) of the Act (to supply specified therapeutic goods or classes of goods, or specified kinds of medical devices, to specified recipients or classes of recipients) to provide a report to the Secretary every six months in relation to the therapeutic goods (including medical devices) supplied under those arrangements.

Item [55] – Subregulation 48(1), definition of *initial decision*, after paragraph (d)
This item amends subregulation 48(1) to include the Secretary's decision under subregulation 10H(9) as a decision that can be the subject of a review under regulation 48 of the TG Regulations.

Item [56] – Schedule 4, Part 1, item 2
This item amends paragraph 2(b) from saying "3 or 4, paragraph 7 (e) or (q) or" to "3, 4, 7 or". This is a consequential amendment that is required following the removal of paragraph 7(q) from Schedule 5 (item [60] below refers).

Item [57] – Schedule 4, Part 1, item 12
This item substitutes a new item 12 in Schedule 4, Part 1, in order to make it clear that a medicine kit can contain medicines and biologicals.

Item [58] – Schedule 5, heading
This item substitutes the current heading for Schedule 5 to "*Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act (subregulation 12(1))"* as a consequence of the amendments in regulation 12 (item [11] above refers). Any biological and therapeutic goods listed in Schedule 5 are exempt from the registration, listing and inclusion of the biological in the Register under Part 3-2A.

Item [59] – Schedule 5, item 1, paragraph (b)
This item amends item 1 of Schedule 5 to the TG Regulations to specify that for a biological to qualify for an exemption set out in item 1 (therapeutic goods that imported for use in the treatment of the importer or the importer's immediate family) the biological must be the subject of an approval under section 32CK of the Act. Section 32CK provides for the approvals granted by the Secretary for importing, exporting or supplying a biological for special and experimental uses.

Item [60] – Schedule 5, item 7
This item amends the current item 7 to remove paragraph 7(q), which refers to human tissue for implantation in the human body, as these products will be captured as Class 2 biologicals under the new regulatory framework for biologicals, and therefore the requirement to exempt these products from entry in the Register will no longer apply.

Item [61] – Schedule 5, item 9
This item substitutes the current item 9 with new items 9 and 10 to allow for biologicals to be exempted from the requirement to be included in the Register under Part 3-2A of the Act when they are used as starting materials in the manufacture of therapeutic goods, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form. The current exemption set out in paragraph (b) of item 9 in relation to medicines that are blood or blood components manufactured by the holder of a licence to manufacture blood and blood components, under this item, are moved to a new item 10 of Schedule 5.

Item [62] – Schedule 5A, heading
This item substitutes the current heading for Schedule 5A with a new heading "*Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act subject to conditions (subregulation 12 (1))"* in order to make it clear that Schedule 5A includes biologicals. This amendment is a consequence of the amendments to regulation 12 set out in item [11] above.

Item [63] – Schedule 5A, items 1 and 1A
This item expands the scope of the exemption under item 1 (from the requirement for registration, listing or inclusion in the Register under Part 3-2A) applying to therapeutic goods imported into Australia that are held under the direct control of the sponsor until the goods are the subject of notification for use in clinical trials, approved for importation, authorised for supply or dispensed as a medicine prescribed for a category A patient under the TG Regulations, with the effect that item also applies to biologicals. This item also expand the coverage of the exemption under item 1A applying to therapeutic goods imported into Australia and held under the direct control of the sponsor, until a decision is made in relation to the entry of the goods in the Register, with the effect that item 1A also applies to biologicals.

Item [64] – Schedule 5A, item 3, paragraph (b)
This item replaces a reference to "Schedule 9" in Schedule 5A to the TG Regulations with "Schedule 9 or item 16 of Schedule 9A", in order to ensure that biologicals used solely for experimental purposes in humans are subject to the relevant notification fees detailed in Schedule 9A.

Items [65] and [66]– Schedule 5A, item 3, paragraph (g) and after paragraph (g)
Item [65] introduces a minor formatting change to item 3, paragraph (b) of Schedule 5A in order to accommodate the inclusion of a new paragraph (h) in item 3, as set out in item [66].

Item [66] adds a new paragraph (h) in column 3 of Schedule 5A in relation to item 3. The effect of this amendment is to require that item 3 of Schedule 5A, which refers to therapeutic goods used solely for experimental purposes in humans (also referred to as the clinical trial notification scheme) may include class 4 biologicals only where one of the following circumstances applies:

- the biological has been approved for use by a national regulatory agency with comparable requirements to Australia's in a clinical trial with an equivalent therapeutic use of the biological; or
- the class 4 biological is supported by clinical evidence received by the TGA.

Such biologicals could, however, be approved for use in clinical trials in humans under paragraph 19(1)(b) of the Act.

Items [67] and [69] – Schedule 5A, item 4, paragraph (b) and Schedule 5A, item 8
These items amend items 4 and 8 of Schedule 5A in order to ensure that biologicals are covered by the exemptions applying to therapeutic goods that are imported by a member of a group of persons visiting Australia for a specified purpose. The amendments also specify that it is a condition of such an exemption that the biological be destroyed, or returned to the consignor, within 1 month of the prescribed circumstances occurring.

Item [68] – Schedule 5A, item 5
This item replaces the reference to 'item 3,' with 'item 3 or biologicals,' in item 5 of Schedule 5A to ensure that biologicals that are manufactured by a person under a contract between the person and a hospital (public and private) or between the person and a public institution under specified conditions are excluded from the operation of this exemption.

Item [70] –Schedule 5A, item 9
This item substitutes a new item 9 to ensure that unused emergency goods dealt with under section 32CG of the Act that are directed by the Secretary to be exported under clause 7 of Schedule 5B are exempt from the requirements for inclusion in the Part 3-2A of the Register.

Item [71] – Schedule 5A, items 10 to 12
This item amends items 10 to 12 of Schedule 5A to replace the reference to 'device –' with 'device or biological –' in each of these subparagraphs, to ensure that in relation to biologicals that are:

- imported into Australia by a medical practitioner or a member of a medical team;
- imported into Australia by a visiting delegation that includes a Head of State or Head of Government of a foreign country; or
- part of the medical supplies of a ship or aircraft visiting Australia;

a person who is responsible for the control and custody of the goods while the group is in Australia is not required to provide the generic name and strength of the active ingredient in the biological.

Items [72] to [109] – Schedule 5B
These items amend Schedule 5B to the TG Regulation to provide for the disposal of unused emergency goods for the purposes of section 32CG of the Act (disposal of unused biologicals).

Item [72] – Schedule 5B, heading
This item substitutes the current heading for Schedule 5 to "*Schedule 5B Disposal of unused emergency goods and unused emergency biologicals (regulation 12AAB)"* as a consequence of the inclusion of provisions relating to the disposal of unused biologicals in Schedule 5B.

Item [73] – Schedule 5B, after clause 1
This item inserts a new clause 1A in Schedule 5B, which requires that a person given a notice by the Minister under paragraph 32CE(b) of the Act (being, a notice varying or revoking an exemption from inclusion in the Register to import, export, manufacture or supply biologicals in order to deal with an emergency) must provide specified information about the biologicals to the Secretary, such as the quantity and location of any unused emergency biologicals over which the person has control. This clause mirrors existing clause 1 of Schedule 5B, which sets

out requirements in relation to therapeutic goods exempted by the Minister from the requirement to be registered or listed in the Register under subsection 18A(1) of the Act.

Item [74] – Schedule 5B, after clause 2
This item inserts a new clause 2A of Schedule 5B to the TG Regulations. The new clause 2A set out steps that a person who has been importing, manufacturing, supplying or exporting biologicals under an exemption under subsection 32CB(1) of the Act must take following the expiry of the period of the exemption. Clause 2A requires such a person to, within 7 days after the end of the exemption, notify the Secretary in writing of the quantity and location of any unused emergency biologicals over which the person has control, and a copy of any records about the biologicals that the person is required to keep.

Item [75] – Schedule 5B, clause 3, heading
This item substitutes the current heading for clause 3 of Schedule 5B, to "*Storage and disposal of unused emergency goods and unused emergency biologicals"* to make it clear that clause 3 of Schedule 5B also applies to biologicals.

Item [76] – Schedule 5B, subclause 3(1)
This item amends subclause 3(1) of Schedule 5B to include reference to unused emergency biologicals, with the effect of making it clear that the requirements relating to the storage and disposal of unused emergency goods set out in subclause 3(1) also apply in relation to unused emergency biologicals.

Items [77] to [87] and [89] to [93] - Schedule 5B, clauses 3 to 7
Items [77] to [87] and [89] to [93] amend clauses 3 to 7 of Schedule 5B to the TG Regulations, which set out requirements relating to the disposal of unused emergency goods, in order to indicate that those requirements also apply in relation to the disposal of unused emergency biologicals for the purposes of section 32CG of the Act. Clause 3 prescribes the requirements relating to the storage and disposal of unused emergency goods and unused emergency biologicals. Clause 4 authorises the Secretary to direct the disposal of unused emergency goods and unused emergency biological. Clause 5 authorises the Secretary to direct that the goods or biological be stored at a specified location and clause 6 authorises the Secretary to direct the unused emergency goods or unused emergency biological be destroyed in specified circumstances. Clause 7 authorises the Secretary to direct that the unused emergency goods or unused emergency biological be exported instead of directing that they be destroyed, if a relevant authority has confirmed its willingness to accept the goods.

Item [88] – Schedule 5B, after paragraph 6(1)(e)
This item introduces a new paragraph 6(1)(ea) to Schedule 5B to the TG Regulations. The new paragraph 6(1)(ea) sets out a requirement that relates specifically to the destruction of unused emergency biologicals, and authorises the Secretary to direct that unused emergency biologicals be destroyed by a specified time if, within 12 months after the emergency exemption ceases, the biological has not been included in the Register under Part 3-2A of the Act, or exempted under section 32CA of the Act from the requirement to be so included or has not been made the subject of an approval or authority under sections 32CK, 32CM or 32CO of the Act in relation to the requirement to be included in the Register.

Items [94] to [103] - Schedule 5B, clause 8
These items amend clause 8 of Schedule 5B in order to indicate that clause 8, which sets out requirements relating to the supply of unused emergency goods, also applies in relation unused emergency biologicals. Clause 8 currently enables the Secretary to direct that the unused

emergency goods that have become registered or listed in the Register, or have become the subject of an approval or authorisation under sections 19 or 19A of the Act, be supplied to an authorised person. An authorised person is defined in subclause 8(3) as being either the person in relation to whom the goods are registered or listed, or the person to whom the approval or authority under sections 19 or 19A of the Act has been given.

Items [104] to [108] - Schedule 5B, clauses 9 and 10

These items amend clauses 9 and 10 of Schedule 5B to the TG Regulations, in order to indicate that these clauses also apply in relation to unused emergency biologicals. Clause 9 of Schedule 5B sets out that a direction given by the Secretary in relation to the export or supply of unused emergency goods under clauses 7 or 8 of Schedule 5B does not affect a person's liability to pay the owner of the goods for that export or supply. Clause 10 of Schedule 5B sets out requirements relating to the keeping of records about unused emergency goods, including that a person with control over unused emergency goods must keep records regarding the quantities of the goods, how the goods are stored and what, if any, actions have been taken to dispose of the goods.

Item [109] – Schedule 5B, clause 11

Clause 11 of Schedule 5B to the TG Regulations currently enables the Secretary to destroy unused emergency goods if a person who has control over the goods has not complied with a provision of Schedule 5B. Item [109] replaces the existing clause 11 with a new clause which includes a reference to unused emergency biologicals in order to make it clear that if a person who has control over any unused emergency goods or unused emergency biologicals has not complied with a provision of Schedule 5B, the Secretary may direct in writing that the goods or biologicals be destroyed by another person.

Item [110] – Schedule 8, items 2 and 3

This item amends items 2 and 3 of Schedule 8 to the TG Regulations in order to clarify that items 2 and 3, which exempt pharmacists, and biomedical engineers, radiochemists and pharmacists in public hospitals who manufacture therapeutic goods in certain circumstances, from the requirement to hold a manufacturing licence, does not apply where the goods involved are biologicals.

Item [111] – Schedule 8, item 5

This item amends item 5 of Schedule 8 to the TG Regulations to allow a person to apply supplementary labelling to a biological where the supplementary label includes only a name and address or the biological number.

Item [112] – Schedule 9, heading

This item substitutes the current heading for Schedule 9 to the TG Regulations with a new heading *"Schedule 9 Fees — therapeutic goods other than biologicals (regulation 43)"*, in order to make it clear that the fees set out in Schedule 9 do not include fees relating to biologicals. Fees for biologicals are detailed in a new Schedule 9A (see item [113]).

Item [113] – After Schedule 9

This amendment inserts a new Schedule 9A titled *"Schedule 9A Fees — biologicals (regulation 43)"*. This new Schedule sets out fees that apply to matters relating to biologicals under the Act or the TG Regulations.

Part 1 of new Schedule 9A sets out definitions of key terms that are used in the table of fees in Part 2 of that Schedule, and Part 2 of the Schedule set out the actual fees.

Item [114] – After Schedule 15

This item introduces a new Schedule 16 to the TG Regulations, which sets out biologicals that are either Class 1, 2, 3 or 4 biologicals under the regulation 2 definitions of Class 1, 2, 3 or 4 biologicals. There are no biologicals mentioned in Schedule 16 on implementation of the biologicals framework, but this Schedule is reserved for future use in that regard.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2011 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provides that the name of the Regulations is the *Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 1)*.

Regulation 2 – Commencement
This regulation provide that the Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*, which will be on 31 May 2011.

Regulation 3 – Amendment of *Therapeutic Goods (Medical Devices) Regulations 2002*
This regulation provides that Schedule 1 amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

Schedule 1 Amendments

Items [1] and [2] – Subparagraph 3.10(3)(a)(ii) and Paragraphs 3.10(3)(b) and (c)
These items amend subparagraph 3.10(3)(a)(ii) and paragraphs 3.10(3)(b) and (c) of the MD Regulations, to make it clear that systems or procedure packs could also include one or more biologicals that are included in the Register under Part 3-2A of the Act.

Items [3], [4] and [5] - Schedule 3, Part 7, paragraphs 7.5(2)(f) and (g) and subparagraph (h)(i)
These items insert the word 'biological' after each mention of 'medicine' in paragraphs 7.5(2)(f) and (g) and subparagraph (h)(i), in order to make it clear that system or procedure packs may include one or more biologicals. Clause 7.5 requires the manufacturer of a system or procedure pack to make a declaration of conformity in relation to the system or procedure pack. These amendments have the effect of requiring a manufacturer to include in the declaration specific requirements about any biologicals in the system or procedure pack.

ATTACHMENT C

DETAILS OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2011 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provide that the name of the Regulations is the *Therapeutic Goods (Charges) Amendment Regulations 2011 (No. 1).*

Regulation 2 - Commencement
This regulation provides that the Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*, which will be on 31 May 2011.

Regulation 3 – Amendment of *Therapeutic Goods (Charges) Regulations 1990*
This regulation provides that Schedule 1 of the Regulations amends the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations).

Schedule 1 Amendments

Item [1] – Subregulation 2(1), after definition of *biological substance*
This item amends subregulation 2(1) in the Charges Regulations to set out definitions of Class 1, 2, 3 and 4 biologicals, and indicates that those terms have the same meanings as set out in the *Therapeutic Goods Regulations 1990.*

Item [2] – After subregulation 3(1A)
This item inserts a new subregulation 3(1AA) to provide for the level of annual charges applicable to a biological whose inclusion in the Register is in force at any time during the financial year. For a Class 1 biological whose inclusion in the Register is in force at anytime during the financial year, the annual charge is $550; and for Class 2, 3 or 4 biologicals whose inclusion in the Register is in force at anytime during the financial year, the annual charge is $5,500.

Item [3] – Regulation 4A
This item removes the provision at regulation 4A that non-profit hospital supply units do not need to pay an annual charge for a manufacturing licence. The exempting of non-profit hospital supply units from fees and charges relating to manufacturing licences and the inspection of manufacturing premises has been subsidised by other therapeutic goods industry and, as such, this exemption is removed to address that concern. To minimise the impact of this change on non-profit hospital supply units, which are largely publicly funded, the Commonwealth Government has agreed to meet the direct regulatory costs of those supply units for the first three years of operation of the new framework.