EXPLANATORY STATEMENT

Select Legislative Instrument 2010 No. 25

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)

Therapeutic Goods Amendment Regulations 2010 (No. 1)

The object of the *Therapeutic Goods Act 1989* (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. In particular, Chapter 4 of the Act establishes a regulatory framework for medical devices. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Subsection 63(1) of 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 Regulations amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to create a specialised regulatory framework for in-vitro diagnostic medical devices (IVD medical devices or 'IVDs').

The Regulations also amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to provide for the transitioning, over a four-year period, from the current regulatory framework for IVDs in those regulations to the new framework.

This new regulatory framework is needed as the current level of regulation of IVDs in Australia is limited. Currently, IVDs for testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) must undergo extensive pre-market review, and a small number of IVDs are required to undergo limited pre-market review. However, the majority of IVDs are not subject to pre-market regulatory scrutiny. The Regulations set out more comprehensive and consistent requirements for IVDs, including by classifying IVDs according to their intended purpose and the public health and personal risks associated with their use.

This new regulatory framework for IVDs also harmonise Australia's regulation of IVD medical devices with those recommended by the medical devices Global Harmonisation Task Force (the GHTF), whose members include the five major regulatory jurisdictions: the United States of America, Europe, Canada, Japan and Australia, and was formed to develop guidelines for a global model of regulation for medical devices.

The Regulations also make a small number of minor changes to the TG Regulations not related to IVDs, such as updating old references in the TG Regulations to Branches of the TGA.

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

In July 2001, the Australian Health Ministers' Advisory Council (AHMAC) endorsed the development of a new regulatory framework for IVD medical devices, to be aligned with international best practice.

Since then, the TGA has undertaken an extensive consultation with industry and other stakeholders in relation to the development of such a framework, including in relation to the proposed Regulations. This consultation has included the establishment of an expert advisory group under the auspices of the National Coordinating Committee on Therapeutic Goods, a subcommittee of AHMAC), a discussion paper circulated to stakeholders seeking comments, presentation and consultation sessions for stakeholders in all States and a number of consultative measures undertaken by a consultancy firm including separate consultations with key stakeholders, a survey of the impact of the proposed new regulatory framework on industry and the preparation of a report on a range of regulatory proposals in relation to IVD medical devices. This consultation process included consultation with stakeholders regarding a range of costs associated with the proposed new regulatory framework, including in relation to proposed fees and charges relating to IVD medical devices.

Further details of this consultation process are set out in the attached document *Regulatory Impact Statement for the implementation of the IVD medical devices regulatory framework*, dated January 2004.

The Act specifies no 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 1 July 2010.

ATTACHMENT A

DETAILS OF THE *THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2010 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provides that the name of the Regulations is the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1).*

Regulation 2 - Commencement
This regulation provides that the Regulations commence on 1 July 2010.

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

Regulation 4 – Definitions for transitional provisions
This regulation sets out a number of definitions for terms mentioned in the transitional arrangements set out in regulations 5, 6 and 7.

Regulation 5 – Transitional – certain devices
This regulation provides for certain transitional arrangements for a diagnostic good for in-vitro use that has previously been declared by the Secretary of the Department of Health and Ageing (the Secretary) not to be a medical device pursuant to subsection 41BD(3) of the Act and was:

- listed or registered under Part 3-2 of the Act;
- subject to an approval under paragraph 19(1)(b) of the Act;
- exempt from listing or registration under Part 3-2 of the Act; or
- a device for which an effective application for listing or registration under Part 3-2 of the Act is pending.

Part 3-2 of the Act provides for the registration and listing of therapeutic goods that are not medical devices. Prior to the introduction of Chapter 4 of the Act in 2002, all therapeutic goods (including devices and medicines) were regulated under the same framework. When Chapter 4 was introduced to create a special regulatory framework for medical devices, a number of devices remained outside the medical device regulatory framework and continued to be regulated together with medicines under Part 3-2.

Paragraph 19(1)(b) of the Act allows the Secretary to grant an approval to a person for the importation into, or the exportation from, Australia or the supply in Australia of specified therapeutic goods (including medical devices) that are not registered goods, listed goods or exempt goods: (a) for use in the treatment of another person; or (b) for use solely for experimental purposes in humans.

Subregulation 5(1) applies certain transitional arrangements to diagnostic goods for in-vitro use as described in that subregulation, being a diagnostic good for in-vitro use that, immediately before 1 July 2010, was:

(a) declared not to be a medical device under subsection 41BD(3) of the Act; and
(b) (i) listed or registered under Part 3-2 of the Act;
(ii) subject to an approval under paragraph 19(1)(b) of the Act;

(iii) exempt from listing or registration under Part 3-2 of the Act; or
(iv) a device for which an effective application for listing or registration under Part 3-2 of the Act has been made but not finally determined.

The relevant transitional arrangements are set out in subregulations 5(2) to 5(7).

The effect of subregulation 5(2) is to apply the amendments set out in Schedule 1 to the Regulations to a device mentioned in subregulation 5(1) after 30 June 2010 for purposes connected with an application for including the device in the Australian Register of Therapeutic Goods (the Register) under Chapter 4 of the Act; or including the device in the Register under Chapter 4 of the Act.

Otherwise, the amendments made by Schedule 1 apply to a device mentioned in subregulation (1) generally after 30 June 2014.

Subregulation 5(3) has the effect of phasing out, by 1 July 2014 or such earlier date on which inclusion of the device in the Register under Chapter 4 takes effect, listings and registrations under Part 3-2 of devices mentioned in subparagraph 5(1)(b)(i) or (iv) by cancelling the listing or registration of the device under Part 3-2 of the Act. A diagnostic good for in-vitro use mentioned in subparagraph 5(1)(b)(i) or (iv) of the Regulations means a diagnostic good for in-vitro use that, immediately before 1 July 2010, was declared not to be a medical device under subsection 41BD(3) of the Act; and which was either registered or listed on the Register under Part 3-2 of the Act or for which an application for registration or listing had been made but not finally determined.

Subregulation 5(4) has the effect of delaying the application of the amendments set out in Schedule 1 of the Regulations until after 30 July 2014 in relation to a diagnostic good for in-vitro use that, immediately before 1 July 2010, was declared not to be a medical device under subsection 41BD(3) of the Act and which was exempt from registration or listing under Part 3-2 of the Act.

Subregulation 5(5) has the effect of delaying the application of the amendments set out in Schedule 1 to the Regulations in relation to certain exempt diagnostic goods for in-vitro use until the exemption that applies to the device ceases to have effect.

Subregulation 5(6) defines when an application is ***finally determined*** for the purposes of the transitional provisions.

Subregulation 5(7) has the effect of clarifying the term ‘finally determined’ as defined in subregulation 5(6) so that it does not include the possibility of a discretion being exercised by a court or tribunal to extend the period for seeking review of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review, in relation to the application of Schedule 1 to the Regulations.

<u>Regulation 6 – Transitional - in-house IVD medical devices</u>
This regulation provides that the amendments made by Schedule 1 to the Regulations only apply to in-house IVD medical devices on 1 July 2014, after the end of the transition period. However, sponsors or manufacturers of in-house IVD medical devices may wish to comply with all the relevant requirements applying to in-house IVD medical devices before 1 July 2014. This regulation has the effect that all applicable obligations, sanctions and measures under the Act and the MD Regulations applying to sponsors and manufacturers of in-house IVD medical devices will only be enforced from 1 July 2014.

Regulation 7 - Transitional – other devices
Under this regulation, the amendments made by Schedule 1 to the Regulations apply after 30 June 2010 to an IVD medical device not mentioned in regulation 5 or 6.

Schedule 1 Amendments

Item [1] – Regulation 1.6
This item substitutes a revised regulation 1.6 which prescribes characteristics for the purposes of paragraph 41BE(1)(e) of the Act. Paragraph 41BE(1)(e) provides that for the purposes of Chapter 4 of the Act, a medical device is taken to be of the same kind as another medical device if they are the same in relation to such characteristics as the regulations prescribe. In relation to a Class 4 IVD medical device (other than an immunohaematology reagent IVD medical device that is a Class 4 IVD medical device), a Class AIMD (Active Implantable Medical Device) medical device and a Class III medical device, such a characteristic will be the unique product identifier given to the device by its manufacturer to identify the device and any variants.

Item [2] – Paragraphs 1.7(a), (b) and (c)
This item adds the specified device nomenclature system codes to be used for IVD medical devices. Subregulation 1.7(1) provides for use of the Global Medical Device Nomenclature (GMDN) Code, as set out in the international standard ISO 15225:2000(E), and defines the level of device nomenclature code to be used for each class of medical device. The GMDN Code is a collection of terms each with a unique code number to describe and catalogue medical devices.

Item [3] – Subregulation 1.7(2), before the definition of *ISO 15225:2000(E)*
This item adds a definition of ***collective term*** to the definitions related to the device nomenclature system codes, being a term used for medical devices that share common characteristics and are identified in the GMDN Code. *Collective term* is used in the Regulations for the purposes of specifying a kind of medical device as it relates to Class 4 immunohaematology reagent IVD medical devices and Classes 1, 2 and 3 IVD medical devices. Examples of the use of a collective term have also been added, to clarify the way in which collective terms are used. As only a select number of the GMDN collective terms are used for the TGA's purposes in regulating IVD medical devices, the definition includes a reference to the TGA document which describes the use of collective terms for the purposes of subsection 41BE(3) of the Act.

Item [4] – Regulations 3.1 and 3.2
This item expands applicable medical device classifications for the purposes of section 41BD of the Act.

New subregulation 3.1(1) describes the hierarchy of medical device classifications and the relationship between classifications for medical devices and IVD medical devices. IVD medical devices are classified as Class 4, Class 3, Class 2 or Class 1, where Class 4 is the highest risk class and Class 1 the lowest risk class. These classes are comparable with, but are not equivalent to, the risk classes AIMD, Class III, Class IIb, Class IIa and Class I for other medical devices (where Class III and AIMD medical devices are of equivalent risk). Such a basis for comparison is necessary in order to classify systems or procedure packs, which may contain both IVD medical devices and medical devices other than IVD medical devices, as the classification of systems or procedure packs is worked out according to the device(s) in the system or procedure pack with the highest level of classification (see item [6]).

New regulation 3.2 provides that a medical device and an IVD medical device have the classifications applying under the classification rules set out in Schedule 2 and 2A respectively (Schedule 2A is added to the MD Regulations by item [48] below).

Item [5] – Subregulation 3.3(2)

This item adds a number of principles for classifying an IVD medical device. Whereas other medical devices are classified in accordance with the intended purpose of the device, taking into account (by means of the classification rules set out in Schedule 2 to the MD Regulations) the site of use in the body, the level of invasiveness and the duration of use, IVD medical devices are classified in accordance with the intended purpose of the device, taking into account the level of personal or public health risk presented by failure of the device to perform as intended.

Item [6] – After subregulation 3.3(7)

This item adds further principles for applying the classification rules to medical device systems or procedure packs.

Subregulation 3.3(8) clarifies that for purposes of classification of a medical device system or procedure pack, medicines are not considered integral to the system or procedure pack. This subregulation is intended to stand in contrast with the classification of other medical devices under clause 5.1 of Part 2 of Schedule 2 to the MD Regulations, which classifies as Class III a medical device that incorporates, or is intended to incorporate, as an integral part, a substance that, if used separately, is a medicine and is liable to act on a patient's body with an action ancillary to that of the device. Class III is the highest level (together with Class AIMD) of risk for medical devices other than IVD medical devices.

Subregulation 3.3(9) clarifies that the classification of a system or procedure pack is the same as the classification of the highest class of medical device or IVD medical device in the system or procedure pack, according to the classification table set out in clause 3.1 (see item [4] above).

Subregulation 3.3(10) classifies a system or procedure pack in accordance with the primary intended purpose of the system or procedure pack in cases where it is not possible to classify the system or procedure pack in accordance with subregulation 3.3(9) because the system or procedure pack contains an IVD medical device(s) and a medical device that is not an IVD medical device that have the same level of classification according to the table in regulation 3.1 (see item [4]).

Subregulation 3.3(11) makes it clear that the references to medical devices in subregulations 3.3(9) and 3.3(10) refer to both IVD medical devices and medical devices other than IVD medical devices.

Item [7] – Subregulation 3.4(3)

This item substitutes the current subregulation 3.4(3) with a redrafted subregulation 3.4(3) and a new subregulation 3.4(4). New subregulation 3.4(3) indicates the classes of devices (that is, Class IIb, IIa and I medical devices, and Class 3, 2 and 1 IVD medical devices) for which manufacturers are required to apply the appropriate conformity assessment procedures, in accordance with new subregulation 3.4(4). The appropriate conformity assessment procedures that are specified under subregulation 3.4(4) are:

- the minimum conformity assessment procedures applicable under Division 3.2 of the MD Regulations; or
- the conformity assessment procedures that are applicable to a medical device classified at a higher level than the device concerned.

Item [8] – After regulation 3.6

This item prescribes the conformity assessment procedures that manufacturers are required to apply to Class 4 in-house IVD medical devices and Class 4 IVD medical devices. New regulation 3.6A does not apply to medical devices used for a special purpose that may fall into these classes. Regulation 3.6A requires a manufacturer of a Class 4 in-house IVD medical device or a Class 4 IVD medical device to apply one of the conformity assessment procedures specified in the new regulation, to that device, but provides a choice as to which of those procedures the manufacturer wishes to apply.

In that regard, regulation 3.6A refers to the full quality assurance procedures (being, those set out in Part 1 of Schedule 3 to the MD Regulations), or the type examination procedures (set out in Part 2 of Schedule 3 to the MD Regulations), together with the production quality assurance procedures (set out in Part 4 of Schedule 3 to the MD Regulations).

Type examination procedures must be applied in conjunction with the production quality assurance procedures so that the procedures relate only to compliance of the product "type" with the nominated standard(s) or specifications, whereas the product quality assurance procedures are directed at ensuring that there is a consistent quality in production.

New regulation 3.6A does not apply to 'medical devices used for a special purpose' that may fall under Class 4 in-house IVD medical devices or Class 4 IVD medical devices. 'Medical devices used for a special purpose' are defined in regulation 3.10 as:

- a device exempt from the operation of Division 3 of Part 4-11 of the Act (offences relating to the requirement for medical devices to be included in the Register) under Division 7.1 and Schedule 4 to the MD Regulations, as amended;
- a medical device subject to approval under section 41HB of the Act (exemptions for specified medical devices approved for import, export or supply for use in the treatment of a person, or for experimental purposes in humans);
- a medical device subject to an authority under section 41HC of the Act (exemptions for medical practitioners); or
- a system or procedure pack to which subregulation 3.10(3) of the MD Regulations applies.

Item [9] – After regulation 3.7

This item prescribes the conformity assessment procedures that manufacturers are required to apply to Class 3 IVD medical devices and Class 3 in-house IVD medical devices, excluding 'medical devices used for a special purpose' (see item [8] above).

New regulation 3.7A has the effect that, in relation to Class 3 IVD medical devices, a manufacturer of such a device must apply either:

(a) the full quality assurance procedures (set out in Part 1 of Schedule 3 to the MD Regulations), except for clause 1.6 of Part 1 of Schedule 3 which requires examination of the design aspect; or

(b) the type examination procedures (set out in Part 2 of Schedule 3 to the MD Regulations), together with the production quality assurance procedures (set out in Part 4 of Schedule 3 to the MD Regulations).

New regulation 3.7A also requires that the type examination procedures cannot be used alone; they must be used in conjunction with the production quality assurance procedures (see item [8]).

New regulation 3.7B requires that for Class 3 in-house IVD medical devices, the manufacturer must apply the procedure specified in Part 6A of Schedule 3 to the MD Regulations (Procedures applying to only certain classes of in-house IVD medical devices). Part 6A of Schedule 3 is added to the MD Regulations by item [62] below.

Item [10] – After regulation 3.8

This item prescribes the conformity assessment procedures that manufacturers are required to apply to Class 2 IVD medical devices and Class 2 in-house IVD medical devices.

The effect of new regulation 3.8A requires the manufacturer of Class 2 IVD medical devices to choose between applying either:

(a) the full quality assurance procedures (set out in Part 1 of Schedule 3 to the MD Regulations), except for clause 1.6 which requires examination of the design aspects; or
(b) the declaration of conformity (not requiring assessment by the Secretary) procedures (set out in Part 6 of Schedule 3 to the MD Regulations) and the production quality assurance procedures (set out in Part 4 of Schedule 3 of the MD Regulations) except for clause 4.7 which relates to a declaration of conformity in relation to that Part.

Although the declaration of conformity procedures do not require assessment by the Secretary, those procedures must be used in conjunction with the applicable parts of the production quality assurance procedures, which must be assessed by the Secretary.

As Part 6 of Schedule 3 already requires a manufacturer to make a declaration of conformity, the declarations required by clause 4.7 are unnecessary for the purposes of regulation 3.8A.

New regulation 3.8B requires the manufacturer of a Class 2 in-house IVD medical device to apply the conformity assessment procedures specified in Part 6A of Schedule 3 (being, conformity assessment procedures that apply to certain classes of in-house IVD medical devices).

Item [11] – After regulation 3.9

This item prescribes the conformity assessment procedures that manufacturers are required to apply to Class 1 IVD medical devices and Class 1 in-house IVD medical devices, excluding ‘medical devices used for a special purpose’ (see item [8] above).

New regulation 3.9A requires that the minimum conformity assessment procedures that must be applied by a manufacturer to a Class 1 IVD medical device, other than a ‘device to be used for a special purpose’, are the declaration of conformity (not requiring assessment by the Secretary) procedures (set out in Part 6 of Schedule 3 to the MD Regulations).

New regulation 3.9B requires the manufacturer of a Class 1 in-house IVD to apply the procedure specified in Part 6A of Schedule 3 to the MD Regulations (Procedures applying to only certain classes of in-house IVD medical devices).

Item [12] – Paragraph 3.10(1)(d)

This item introduces a formatting change to account for the addition of a new paragraph 3.10(1)(e) to regulation 3.10 by item [13] below.

Item [13] – After paragraph 3.10(1)(d)

This item adds (at new paragraph 3.10(1)(e)) a system or procedure pack containing at least one medical device (that is not an IVD medical device) and at least one IVD medical device to the list

of ‘medical devices for a special purpose’. This has the effect of applying the conformity assessment procedures for system or procedure packs under Schedule 3, Part 7, clause 7.5 to the system or procedure pack containing at least one medical device (that is not an IVD medical device) and at least one IVD medical device, thereby ensuring that the system or procedure pack is covered by a declaration of conformity made in accordance with clause 7.5.

Item [14] – Subregulation 3.10(1), note for paragraphs (d) and (e)
This item revises the *Note* currently at and relating to 3.10(1)(d). This ensures that there is no confusion as to the classification and applicable conformity assessment procedures for system or procedure packs in cases where the new paragraph 3.10(1)(e) or the existing subregulation 3.10(3) does not apply. In such a case, the device is required to be classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A to the MD Regulations and the conformity assessment procedures that are required to be applied are the procedures that apply to the relevant classification.

The new *Note* also includes a paragraph relating to new paragraph 3.10(1)(e) (see item [13] above), which make it abundantly clear that a system or procedure pack that *does* contain both a medical device (that is not an IVD medical device) and an IVD medical device be treated as a single device. The system or procedure pack still be classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A to the MD Regulations, but the conformity assessment procedures that be required to be applied be the procedures for ‘medical devices used for a special purpose’ in Part 7 of Schedule 3 to the MD Regulations.

Item [15] – After subregulation 3.10(1)
This item has the effect that the conformity assessment procedures for ‘medical devices used for a special purpose’ mentioned in regulation 3.10 not apply to a manufacturer of Class 1, 2 and 3 in-house IVD medical devices. This item also insert a *note* to explain that the conformity assessment procedures that are required to be applied to Class 1, 2 and 3 in-house IVD medical devices are the procedures mentioned in Part 6A of Schedule 3 to the MD Regulations.

Item [16] – Subregulation 3.10(2), note
This item removes the note after regulation 3.10(2) related to the regulation of custom-made medical devices, since the time period specified in the note has expired and so is no longer relevant.

Item [17] – Paragraphs 4.1(2)(a), (b), (c) and (d)
This item has the effect of excluding IVD medical devices from the provisions of paragraphs 4.1(2)(a), (b), (c) and (d). These paragraphs specify, for the purposes of paragraph 41EA(b) of the Act, kinds of medical devices for which a conformity assessment certificate must be issued before a valid application may be made for inclusion of the devices in the Register. These provisions are based on the risk of medical devices of these kinds. However, in the case of IVD medical devices containing the materials specified in these paragraphs the risks are not considered to be high and are not such as to require the TGA to conduct the conformity assessment certification process.

Item [18] - Paragraph 4.1(2)(d)
This item introduces a formatting change to account for the addition of a new paragraph 4.1(2)(e) to subregulation 4.1(2) by item [19] below.

Item [19] – After paragraph 4.1(2)(d)
This item (at new paragraph 4.1(2)(e)) requires Class 4 in-house IVD medical devices and Class 4 IVD medical devices manufactured outside Australia to have a conformity assessment

certificate issued before a valid application can be made for those kinds of medical devices to be included in the Register.

Item [20] – Subparagraph 4.1(3)(a)(v)
This item introduces a formatting change to allow for the addition of a new subparagraph 4.1(3)(a)(v) to subregulation 4.1(3) by item [21] below.

Item [21] – After subparagraph 4.1(3)(a)(v)
This item (at new subparagraph 4.1(3)(a)(vi)) excludes Class 1, 2 or 3 in-house IVD medical devices and Class 1 IVD medical devices manufactured outside Australia, or the manufacturer of these kinds of devices, from the requirement to have a conformity assessment certificate issued before a valid application can be made for those kinds of medical devices to be included in the Register.

Item [22] – Paragraph 5.3(1)(i)
This item introduces a formatting change to allow for the addition of a new paragraph 5.3(1)(j) to subregulation 5.3(1) by item [23] below.

Item [23] – After paragraph 5.3(1)(i)
This item specifies (at new paragraph 5.3(1)(j)) that for the purposes of paragraph 41FH(1)(a) of the Act certain IVD medical devices for which an application for inclusion of those devices in the Register must be selected for auditing.

The kinds of IVD medical devices whose applications are selected for auditing pursuant to paragraph 41FH(1)(a) of the Act (subject to cases where a conformity assessment certificate has been issued, and has not been suspended or revoked, in respect of the kind of medical device) be:

- non assay-specific quality control material that is intended for monitoring a Class 4 IVD medical device, since these are, by means of the Item [47] below, classified as Class 2, but be considered to require a high level of performance;
- an IVD medical device that is intended for self-testing, to ensure that the level of performance, labelling and usability are suitable for use by a lay person;
- an IVD medical device that is intended for point of care testing, to ensure that the level of performance, control mechanisms and usability are suitable for use outside a controlled laboratory environment;
- a Class 3 IVD medical device that is intended for detecting the presence of, or exposure to, a sexually transmitted agent, since these have a potential public health risk, as well as a high personal risk;
- an IVD medical device for managing and monitoring the treatment of infections, diagnosed using a Class 4 IVD medical device (for example, quantitative nucleic acid test (NAT) and genotyping assays for HIV and HCV), to ensure a continuing level of high performance from these IVD medical devices, which have to date been registrable under the existing regulatory framework;
- an IVD medical device selected for a national screening program, to ensure a suitable level of performance in a public health context; or
- an IVD medical device that is to be supplied as a pharmaceutical benefit, to ensure a suitable level of performance in a public health context;
- an IVD manufactured overseas where the Secretary is not satisfied in accordance with subregulation 3.5(1) that the conformity assessment procedures have been performed by a body with the authority and expertise to perform that function.

Item [24] – Schedule 1, after subclause 2(2)
This item defines, for the purposes of clarifying paragraph 2(d) of the MD Regulations, the term ***residual risk*** to clarify the intention of the provision to require manufacturers of a medical device to inform users of any risks that remain after the measures described in paragraphs 2(2)(a) to (c) have been applied in the design and construction of the device.

Item [25] – Schedule 1, clause 6, heading
This item changes the heading of clause 6 to align with a wording change in the clause (see item [26] below).

Item [26] – Schedule 1, clause 6
This item removes the word "side" from clause 6 so that it refers to "undesirable effects", which encompass the additional range of possible negative effects on users owing to IVD medical devices. An example might be an inaccurate diagnostic measurement from an IVD medical device that does not produce a side effect in the user but has an undesirable effect on that user.

Item [27] – Schedule 1, paragraph 7.1(b)
This item expands paragraph 7.1(b) of the MD Regulations to insert the words "and specimens" to encompass the use of IVD medical devices on specimens.

Item [28] – Schedule 1, paragraph 8.1(2)(b)
This item expands subclause 8.1(2) by splitting paragraph (b) into new paragraphs (b) and (c), so that the new paragraphs encompass IVD medical devices; separating the concepts in paragraph (b) provides additional clarity.

Item [29] – Schedule 1, clause 8.2, heading
This item changes the heading of clause 8.2 to align with new wording in the clause (see item [30] below).

Items [30] and [31] – Schedule 1, paragraphs 8.2(1)(a) and (b), and subclauses 8.2(2), (3) and (4)
These items replace each mention of "tissues, cells" in paragraphs 8.2(1)(a) and (b), and subclauses 8.2(2), (3) and (4) of the MD Regulations with "tissues, tissue derivatives, cells" in order to capture the full range of substances which these clauses are intended to cover.

Item [32] – Schedule 1, clause 8.2, at the foot
This item inserts a note at the foot of clause 8.2 to clarify that subclause 8.2(5) of the MD Regulations may not apply to certain IVD medical devices, for instance those where inactivation of the viruses or transmissible agents is inappropriate and interferes with the intended purpose of the device.

Item [33] – Schedule 1, paragraph 9.2(g)
This item introduces a formatting change to allow for the insertion of a new paragraph 9.2(h) of the MD Regulations (see item [34] below).

Item [34] – Schedule 1, after paragraph 9.2(g)
This item inserts new paragraph 9.2(h) to cover risks associated with disposal of waste substances. This amendment applies to all medical devices and fills a gap in the list of risks of use of a medical device to be considered by the manufacturer, by requiring that a medical device be designed and produced in a way that ensures that, as far as practicable, (among other risks) the risks associated with disposal or any waste substances are removed or minimised.

Item [35] – Schedule 1, subclause 12.13(1)
This item expands subclause 12.13(1) of the MD Regulations by replacing the words "display a code that can be used" with "incorporate, display, emit or exhibit a code or unique characteristic" in order to provide greater flexibility in the way a manufacturer may enable identification of an active implantable medical device.

Item [36] – Schedule 1, subclause 12.13(2)
This item changes the word "code" to "code or characteristic", to correspond with the new wording that is introduced by item [35] below.

Item [37] – Schedule 1, after subclause 13.1(3)
This item inserts a note after subclause 13.1(3) of the MD Regulations with the effect of providing greater flexibility in the way a manufacturer may provide information required to be provided with a medical device, by allowing the use of drawings or diagrams in product information. It is intended that drawings or diagrams be additional to, and not replace, written instructions, in relation to medical devices.

Item [38] – Schedule 1, clause 13.3, table, item 8
This item expands item 8 of the table in clause 13.3 of the MD Regulations by replacing the words "particular individual and is intended for use only by that individual" with "particular individual or health professional and is intended for use only by that individual or health professional". This aligns the wording of this item with the revised definition of "custom-made" (see item [91] below).

Item [39] – Schedule 1, clause 13.3, table, item 9
This item expands item 9 of the table in clause 13.3 of the MD Regulations to require, where applicable, the information to be provided with an IVD medical device to indicate that it is intended for performance evaluation only. The term "performance evaluation" is used for IVD medical devices rather than "pre-market clinical investigation".

Item [40] – Schedule 1, paragraph 13.4(2)(a)
The effect of this item allows, as is already the case with Class I and Class IIa medical devices, devices that are Class 1 IVD medical devices to be provided with instructions or with abbreviated instructions, if the device can be used safely for its intended purpose without instructions.

Item [41] – Schedule 1, subclause 13.4(3), table, item 9
This item expands item 9 of the table in subclause 13.4(3) of the MD Regulations to align the wording of that item, which relates to requirements for instructions for use for a custom-made medical device, with the revised definition of "custom-made" referred to in the Regulations (see item [91] below).

Iitem [42] - Schedule 1, subclause 13.4(3), table, item 10
This item expands item 10 of the table in subclause 13.4(3) of the MD Regulations to require, where applicable, that instructions for use required to be provided with an IVD medical device to indicate that the device is intended for performance evaluation only. The term "performance evaluation" is used for IVD medical devices rather than "pre-market clinical investigation".

Item [43] – Schedule 1, subclause 13.4(3), table, after item 25
This item inserts a new item 25A in the table to require that instructions required to be provided with a medical device (other than an IVD medical device) contain information about non-viable animal tissues and recombinant and microbial substances that are included with the device. The insertion of this requirement aligns with the recommendations of the GHTF.

Item [44] – Schedule 1, subclause 13.4(3), table, after item 28
This item inserts a new item 29 in the table to require, if applicable, that instructions required to be provided with an IVD medical device include information related to the use and performance of the device, including details of the scientific principle of the test, type of specimen to be used, test procedures, performance characteristics and any precautions to be taken if the IVD medical device contains, or is used with, substances or materials that present a risk of infection.

Item [45] – Schedule 1, after clause 14
This item inserts a new clause 15 of the MD Regulations to set out the essential principles for design and construction that applies to IVD medical devices only.

This amendment reflects the unique nature of IVD medical devices and takes into account the differences between IVD medical devices and other medical devices.

This amendment requires that an IVD medical device be designed and produced in such a way as to ensure that:

- the intended use of the device is supported by analytical and clinical characteristics – that is, the device is fit for the purpose;
- the required performance characteristics have been taken into account when designing and developing the device;
- the values assigned to calibrator and control materials are traceable through the manufacturer's quality management system;
- the performance of the device can be verified by the user as far as reasonably practical; and
- devices used for self-testing are designed and manufactured to take into account the skills and means available to the user and any reasonable variations due to the user's technique and environment at the same time as reducing the risk of error, and include product information that is easily understood.

Item [46] – Schedule 2, heading
This item substitutes a revised heading for Schedule 2 to the MD Regulations (the current heading "Classification rules" is replaced with "Classification rules for medical devices other than IVD medical devices") to make it clear that the medical device classification rules set out in this Schedule are not to be applied to IVD medical devices.

Item [47] – Schedule 2, clause 5.8
This item revises clause 5.8 to clarify that, despite any other classification rules in Schedule 2 to the MD Regulations, a medical device that is intended for export from Australia, and not for supply in Australia, is a Class I medical device. The effect of this amendment is to clarify and remove any doubt in relation to the intended effect of clause 5.8.

Item [48] – After Schedule 2
This item inserts new Schedule 2A "Classification rules for IVD medical devices" to add rules for the classification of IVD medical devices for the purposes of subregulation 3.2(2) (see item [4] above].

Clause 1.1 – Detection of transmissible agents posing a high public health risk
This rule classifies IVD medical devices intended to be used for the detection of transmissible agents posing a high public health risk as Class 4. This rule applies to a device that is intended for use in:

- screening for transmissible agents in blood, blood components and tissue for transfusion or transplantation; and
- detecting the presence of or exposure to a transmissible agent that causes a serious disease with a high risk of propagation in the Australian population.

Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is a major determinant as to whether the donation/product be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Clause 1.2 – Detection of red blood cell antigens and antibodies and non-red cell typing
This rule classifies as Class 3 IVD, medical devices reagents intended to be used for detecting red blood cell antigens and antibodies for determining suitability for transfusion or for non-red cell typing for the purposes of transplantation of tissue, except where they are otherwise specified as being in Class 4.

Blood grouping reagents used to determine high risk blood groups and assess suitability for transfusion or transplantation will be Class 4 IVD medical devices. High risk blood groups are regarded as the ABO system [A (ABO1), B (ABO2) & AB (ABO3)] Rhesus system [D (RH1), C (RH2), E (RH3), c (RH4), & e (RH5)]; Kell system (K), Duffy system [Fy^a (FY1) & Fy^b (FY2)] and the Kidd system [Jk^a (JK1) & Jk^b (JK2)].

The rule divides blood grouping IVD medical devices into two subsets depending on the nature of the blood group antigen the IVD is designed to detect, and its importance in a transfusion setting.

Clause 1.3 – Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk
This rule applies to an IVD medical device used to:

- diagnose serious infectious diseases where there is a risk of propagation in the community;
- determine immune status;
- monitor levels of medicines, substances or biological components;
- screen for genetic or congenital disorders;
- diagnose cancer; or
- manage the treatment of patients suffering from a life-threatening disease.

Under this rule, an IVD medical device is classified as a Class 3 IVD medical device if the device is intended to be used in situations where an erroneous result puts the patient in an imminent life-threatening situation or has a major negative impact on the patient outcome, or, where a device provides the critical or sole determinant for the correct diagnosis. However, if the device is used only for monitoring or a therapy decision is usually made only after further investigation, it is classified as a Class 2 IVD medical device.

Clause 1.4 – IVD medical devices for self-testing
This rule classifies IVD medical devices for self-testing as Class 3 IVD medical devices unless they are not intended to determine a serious condition or the examination is preliminary and follow-up additional testing is required. In that case, other classification rules set out in Schedule 2A applies.

Clause 1.5 – Non assay-specific quality control material

This rule classifies quality control material which is not linked to a particular IVD medical device as Class 2 IVD medical devices, despite classification rules 1.1 to 1.4. These control materials may be used with a number of IVD medical devices from the same or different manufacturers and provide a general indication that the assay is performing correctly. Such controls are not used to validate the results released for individual patients and so do not need to be classified at the level of the assay(s) with which they may be used.

Clause 1.6 – Reagents, instruments etc

This rule classifies as Class 1 IVD medical devices certain equipment such as instrumentation, reagents, specimen receptacles and microbiological culture media that are specifically intended for in-vitro diagnostic testing, despite classification rules 1.1 to 1.5. These devices are considered to present a low individual risk and no or minimal public health risk. However, a product for general laboratory use is not an IVD medical device unless the product is specifically intended by its manufacturer to be used for in-vitro diagnostic examination.

Clause 1.7 – Other IVD medical devices are Class 2 IVD medical devices

This rule classifies an IVD medical device not mentioned elsewhere in Schedule 2A to the MD Regulations as a Class 2 IVD medical device; unless another clause in that Schedule applies to classify the device at a higher level. This is a "catch all" rule designed to ensure that all IVD medical devices are covered by the classification rules.

Clause 1.8 – IVD medical devices intended for export only

This rule classifies an IVD medical device that is intended for export from Australia, and not for supply in Australia, as a Class 1 IVD medical device. As such IVD medical devices are likely be required to meet the regulatory requirements in the importing jurisdiction, it is considered that the full regulatory requirements for supply in Australia will not need to be met in relation to such devices. However, the manufacturer of such a device will in such circumstances, be required to ensure compliance with the essential principles for safety and performance.

Item [49] – Schedule 3, paragraph 1.1(b)

This item revises paragraph 1.1(b) of Schedule 3 to the MD Regulations to include a reference to a Class 4 in-house IVD medical device and a Class 4 IVD medical device in that paragraph. The effect is to enable the conformity assessment procedures on the examination of the design of certain medical devices in clause 1.6 of Schedule 3 (which deals with examination of the design of certain medical devices) to apply to a Class 4 in-house IVD medical device and a Class 4 IVD medical device as per regulation 3.6A (see item [8] above) if the conformity assessment procedures specified in Part 1 of this Schedule are applied to these types of IVD medical devices.

Item [50] – Schedule 3, subparagraph 1.4(5)(c)(vi)

This item avoids the need to revise subparagraph 1.4(5)(c)(vi) of Schedule 3 to the MD Regulations with the effect that details of non-viable tissues, cells or substances of animal origin or microbial and recombinant substances do not need to be included in the quality system documentation for IVD medical devices. This is because such materials are very common in IVD medical devices and their use is covered specifically in technical documentation.

Item [51] – Schedule 3, after subparagraph 1.4(5)(c)(vi)

This item inserts new subparagraph 1.4(5)(c)(via) to require details of viable tissues, cells or substances of animal origin to be included in the quality system documentation for IVD medical devices. The use of viable tissues, cells or substances in a device which is not an IVD medical device removes that device from the requirements of Chapter 4 of the Act, by means of the Therapeutic Goods (Articles that are not Medical Devices) Order No 1 of 2004. These

substances, however, may be used in IVD medical devices and, if so, it is considered that the origins of such material should be documented in the quality system documentation.

Item [52] – Schedule 3, clause 1.6, heading

This item replaces the heading to clause 1.6 of Schedule 3 to the MD Regulations, with "Examination of design of Class 4 in-house IVD medical device, Class 4 IVD medical device, Class AIMD medical device or Class III medical device". This is designed to complement the amendment detailed in item [53] below.

Item [53] – Schedule 3, subclause 1.6(1)

This item inserts a new reference to Class 4 in-house IVD medical devices and Class 4 IVD medical devices to expand the range of devices which is required for examination of their design under Part 1 of Schedule 3 by including Class 4 in-house IVD medical devices and Class 4 IVD medical devices in that range. In addition a manufacturer of a device mentioned in subclause 1.6(1) is required to arrange for the independent examination of the design or intended performance of the relevant kind of device; to detail the information and documentation that the manufacturer must have available; and also has obligations in relation to taking certain actions in the event of changes to the device's design or intended performance.

Item [54] – Schedule 3, subclause 1.6(5), note

This item substitutes a revised note to state that for the purposes of Division 3.2 of the MD Regulations, examination of the design of Class 2 and 3 IVD medical devices is not required.

Item [55] – Schedule 3, paragraph 1.9(1)(c)

This item inserts a new reference to require a manufacturer whose quality management system for a Class 4 in-house IVD medical device or a Class 4 IVD medical device has been assessed under clause 1.3 to keep the information and documentation required under subclause 1.6(3) of Schedule 3 (being, written information in relation to the design, the production process and the intended performance of the kind of device). Current subclause 1.9(2) notes that the specified records must be kept for at least five years after the manufacture of the last medical device to which the quality management system was applied. Current subclause 1.9(3) makes it clear that the manufacturer must make the specified records available to the Secretary on request.

Item [56] - Schedule 3, paragraph 2.3(3)(j)

This item amends the paragraph 2.3(3)(j) to avoid the need for details of non-viable tissues, cells or substances of animal origin or microbial and recombinant substances to be included in the quality system documentation for IVD medical devices (see item[51] above).

Item [57] – Schedule 3, after paragraph 2.3(3)(j)

This item inserts a new paragraph 2.3(3)(ja), that the requirement of details of viable tissues, cells or substances of animal origin be included in the quality system documentation for IVD medical devices (see item [51] above).

Item [58] – Schedule 3, subclause 4.7(1)

This item expands subclause 4.7(1) to require a manufacturer of a Class 4 in-house IVD, a Class 4 IVD medical device or a Class 3 IVD medical device for which a quality management system has been assessed under clause 4.3, to make a declaration of conformity in relation to the kind of device.

Item [59] – Schedule 3, subclause 4.7(1), note

This item revises the note to subclause 4.7(1) to the effect that a declaration of conformity under clause 4.7 will not be required for a Class 2 IVD medical device. This is needed because a declaration of conformity under Part 6 (not requiring assessment by the Secretary) is already required for the purposes of Division 3.2 of the MD Regulations.

Item [60] – Schedule 3, paragraph 4.8(1)(c)

This item revises paragraph 4.8(1)(c) to require a manufacturer whose quality management system for a Class 4 in-house IVD medical device or a Class 4 IVD medical device to keep the declaration of conformity required under clause 4.7 of Schedule 3 to the MD Regulations (being, a declaration relating to matters including the name and business address of the manufacturer and details of any conformity assessment standard applied to the relevant quality management system). Current subclause 4.8(2) notes that the specified records must be kept for at least five years after the manufacture of the last medical device to which the quality management system was applied. Current subclause 4.8(3) makes it clear that the manufacturer must make the specified records available to the Secretary on request.

Item [61] – Schedule 3, after subparagraph 6.6(2)(h)(i)

This item inserts a new requirement for a manufacturer of a Class 2 IVD medical device for which technical documentation is prepared under Part 6 of Schedule 3 to the MD Regulations, to make a declaration of conformity, and that this declaration include the matters mentioned in subclause 6.6(2) including the information required at current subparagraphs 6.6(2)(h)(iv) and (v) which relate principally to details of the conformity assessment certificates held in relation to the kind of device.

Item [62] – Schedule 3, after Part 6

This item inserts a new Part 6A to the MD Regulations to add the conformity assessment procedures that apply to certain classes of in-house IVD medical devices.

Clause 1.2 of Part 6A, requires that a manufacturer of a Class 3, Class 2 or Class 1 in-house IVD medical device must:

- notify the Secretary on a day (the notification day) no later than 1 July 2014 and then annually on a day no later than the notification day, of the contact details of the laboratory and the in-house IVD medical devices manufactured by the manufacturer;
- in the case of a laboratory that manufactures an in-house IVD medical device, meet the National Pathology Accreditation Advisory Council (NPAAC) performance standard *Requirements for the Development and Use of In-house In-vitro Diagnostic Devices (IVD)s* as amended from time to time;
- in the case of a laboratory that manufactures an in-house IVD medical device, be accredited as a medical testing laboratory by the National Association of Testing Authorities (NATA) or by a conformity assessment body determined by the Secretary;
- in the case of a laboratory that manufactures an in-house IVD medical device, meet the standard published by the International Organisation for Standardization known as ISO 15189 - *Medical laboratories - Particular requirements for quality and competence* as amended from time to time.

Clause 1.2 also sets out that it is an offence for a manufacturer to not notify the Secretary on a day (the notification day) no later than 1 July 2014 and then annually on a day no later than the notification day, of the contact details of the laboratory and the in-house IVD medical devices manufactured by the manufacturer, with a penalty of 10 penalty units. The Criminal Law Branch

of the Attorney-General's Department was consulted in relation to this offence and noted that it did not raise any criminal law policy concerns.

Clause 1.3 requires manufacturers of Class 3, Class 2 or Class 1 in-house IVD medical devices to give the Secretary information on a range of specified matters about the relevant quality management system or the kinds of IVD medical devices manufactured under the system if asked to do so by an authorised person, and to arrange for testing to be undertaken to ensure that the quality management system is operating effectively if asked to do so by an authorised person.

Clause 1.4 require a manufacturer of a Class 3, Class 2 or Class 1 in-house IVD medical device, to establish and maintain a post-marketing system that complies with subclause 1.4(2) for monitoring and reporting and corrective action in relation to the post-production phase of the device. Subclause 1.4(2) sets out various features of the post-marketing system that manufacturers are required to maintain, such as requiring the manufacturer to systematically review experience gained in the post-production phase for relevant medical devices and requiring the manufacturer to implement appropriate means to apply any necessary corrective action for the design or production of such devices.

Item [63] – Schedule 3, paragraph 7.2(2)(c)
This item revises the wording of this paragraph with the new definition of "custom-made" (see item [91] below).

Item [64] – Schedule 4, item 1.1
This item expands the scope of item 1.1 to exempt a medical device that is imported into Australia for use in the in-vitro examination of a specimen obtained from the importer or a member of the importer's immediate family, provided the conditions in subparagraphs 1.1(a) to (d) are met.

Items [65] and [66] – Schedule 4, subparagraphs 1.1(b)(i) and 1.1(b)(ii)
Paragraph 1.1(b) of Part 1 of Schedule 4 to the MD Regulations, currently exempts the kinds of devices that incorporate animal material or human blood or plasma from inclusion in the Register where an approval has been given under section 41HB of the Act. These items omit IVD medical devices from this exemption.

Item [67] – Schedule 4, paragraph 1.1(c)
Paragraph 1.1(c) of Part 1 of Schedule 4 to the MD Regulations, currently exempts certain devices from inclusion in the Register where the quantity imported in one importation is no more than three months supply and the total quantity imported in a 12-month period is no more than 15 months supply.

Item [67] also specifies the classes of all the devices to which the paragraph applies, namely Class 4 IVD, Class AIMD, Class III, Class 3 IVD, Class IIb, Class 2 IVD and Class IIa medical device.

Item [68] – Schedule 4, after item 2.9
Part 2 of Schedule 4 lists medical devices that are exempt from inclusion in the Register provided the conditions set out in the Part are met.

New item 2.10 adds an exemption for Class 1, Class 2 and Class 3 in-house IVD medical devices that meet conditions set out at paragraphs (a) to (h) of new item 2.10. They include conditions that the device comply with the essential principles; the manufacturer must apply the appropriate conformity assessment procedures (being, those procedures set out in new

Part 6A of Schedule 3) at all times; and the manufacturer of a relevant device, upon request, provide samples of the devices and a range of specified information about the device to the Secretary.

Item [69] – Schedule 5, item 1.2
This item adds a fee to item 1.2 for a surveillance audit related to a conformity assessment certificate for an IVD medical device, in accordance with subsection 41EJ(4) of the Act. The fee is $6,970.

Item [70] – Schedule 5, item 1.3
This item amends column 2 of item 1.3 of Part 1 of Schedule 5 to the MD Regulations to refer to review of a conformity assessment certificate for a medical device, other than an IVD medical device, in order to make it clear that the fee at item 1.3 is intended to apply in respect of medical devices other than IVD medical devices.

Item [71] – Schedule 5, after item 1.3, new item 1.3A
This item adds fees that are payable for reviewing a conformity assessment certificate in relation to an IVD medical device, under subsection 41EJ(4) of the Act. The fees are $23,900, $51,000, $12,500, $3,010, $33,000 and $21,000. Each fee relates to the review of different provisions of Schedule 3 to the MD Regulations

Item [72] – Schedule 5, item 1.4
This item extends the provision for fees for reviewing a submission in relation to a cancelled conformity assessment certificate to cover IVD medical devices.

Item [73] – Schedule 5, paragraph 1.5(e)
This item introduces a formatting change to accommodate the addition of a new paragraph 1.5(f) into Schedule 5 to the MD Regulations.

Item [74] – Schedule 5, after paragraph 1.5(e)
This item adds a new fee for an application to include an IVD medical device, including Class 4 in-house IVD medical devices, in the Register. The fee is $790.

Item [75] – Schedule 5, items 1.6 to 1.8
The fees at items 1.6, 1.7 and 1.8 relate to, respectively, considering a submission made to the Secretary in relation to a suspension of a kind of medical device from the Register (item 1.6), application for approval to use a specified kind of medical device for experimental purposes in humans (item 1.7) and notification of an intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans (item 1.8). This item revises the fees for these items so that they apply to an IVD medical device.

Item [76] – Schedule 5, item 1.9
This item makes it clear that the fees set out at item [9] above, which relates to initial assessments in relation to conformity assessment procedures applying under various provisions of Schedule 3 to the MD Regulations, apply to medical devices other than IVD medical devices.

Item [77] – Schedule 5, after item 1.9
This item adds new item 1.9A to provide for fees that are payable in relation to an initial assessment of conformity assessment procedures for IVD medical devices under Schedule 3 to the MD Regulations, under subsections 41LA(1) and (2) of the Act. The fees are $23,900, $51,000, $12,500, $3,010, $33,000 and $21,000. Each fee relates to an initial conformity

assessment for an IVD medical device in relation to different provisions of Schedule 3 to the MD Regulations which sets out conformity assessment procedures.

Item [78] – Schedule 5, item 1.10

This item makes it clear that the fees set out in this item, which relate to conformity assessments under various provisions of Schedule 3 to the MD Regulations consequent upon a change to a medical device or to a quality management system applied to a medical device, apply to medical devices other than IVD medical devices.

Item [79] – Schedule 5, after item 1.10

This item adds new fees for initial conformity assessments under various provisions of Schedule 3 to the MD Regulations consequent upon a change to an IVD medical device or to a quality management system applying to a medical device. The fee is 60 per cent of the equivalent fee for those provisions set out in new item 1.9A (see item [77] above).

Item [80] – Schedule 5, item 1.12

This item extends the scope of item 1.12 to IVD medical devices, to provide fees for supplementary assessments of IVD medical devices under new items 1.9A and 1.10A (see items [77] and [79] above).

Item [81] – Schedule 5, after item 1.14

This item adds a fee for conducting an application audit assessment for a Class 1, Class 2 or Class 3 IVD medical device. The fee is $5,500.

Item [82] – Schedule 5, item 1.15

Item 1.15 sets a fee for an application for the consent of the Secretary to import, supply or export a medical device under section 41MA of the Act. (Section 41MA deals with criminal offences for importing, supplying or exporting a medical device that does not comply with the essential principles). This item makes it clear that the fee applies to applications related to IVD medical devices.

Item [83] – Schedule 5, after item 1.16

This item adds a fee that applies to a laboratory when notifying the TGA, initially and annually, of Class 1, 2 or 3 in-house IVD medical devices manufactured by the laboratory, in accordance with the provisions of Part 6A of Schedule 3. The fee is $810.

Item [84] – Schedule 5, clause 2.1

This item extends the scope of the additional fees of travel costs and reasonable expenses of assessors involved in initial conformity assessments and assessments consequent on a change to a medical device or a quality management system in relation to IVD medical devices under new items 1.9A and 1.10A.

Item [85] – Schedule 5, subclause 2.2(1)

This item amends clause 2.2 of Schedule 5 to the MD Regulations to extend the scope of the additional fee for the cost of testing kinds of medical devices to new items 1.3A(e) and 1.9A(e) mentioned in items [71] and [77] above.

Items [86], [87], [90], [92], [93], [100] and [103] to [105] – Dictionary, definitions

These items introduce a formatting change relating to punctuation in the definitions:

- *Active implantable medical device*
- *authorized person*
- *conformity assessment certificate*

- *device nomenclature system code*
- *ethics committee*
- *production quality assurance procedures*
- *product quality assurance procedures*
- *refurbishment*
- *sponsor*
- *variant,* and
- *working day.*

Item [88] – Dictionary, definition of *central circulatory system*, paragraph (p)
This item substitutes paragraph (p) in the definition of *central circulatory system* in the Dictionary, to include the common iliac artery, which was inadvertently omitted from the MD Regulations.

Item [89] – Dictionary, after definition of *classification rules*
This item adds, after the definition of *classification rules* in the Dictionary, definitions for *Class 1 in-house IVD medical device, Class 1 IVD medical device, Class 2 in-house IVD medical device, Class 2 IVD medical device, Class 3 in-house IVD medical device, Class 3 IVD medical device, Class 4 IVD in-house IVD medical device* and *Class 4 IVD medical device*. Each of those definitions is in accordance with the classifications of each of the relevant IVD medical devices mentioned set out in Division 3.1 of Part 3 of the MD Regulations.

Item [91] – Dictionary, definitions of *Conformity assessment standard*, *current poisons standard* and *custom-made medical device*
This item introduces formatting changes relating to punctuation to the definitions of *conformity assessment standard* and *current poisons standard* in the Dictionary.

It also introduces a revised definition of *custom-made medical device* in that Dictionary to include, not only a medical device manufactured in accordance with a request from a health care professional specifying design characteristics specifically for use by a named individual, but also a medical device made in accordance with a request from a health care professional specifying design characteristics specifically for use by the health care professional to meet special needs arising in the course of his or her practice. An example of the expanded circumstances where the definition applies is a device configured especially to aid use by the health care professional, for instance a left-handed instrument. This provision is not intended to cover commercial manufacture of, for instance, procedure packs, which may be made to a specification supplied by a hospital or health care practice.

Custom-made devices are exempt from inclusion in the Register, but are still be required to meet the essential principles (of safety and performance) as far as possible, and comply with the conformity assessment procedures for custom made medical devices.

Item [94] – Dictionary, definition of *Health professional*
This item introduces a formatting change relating to punctuation to the definition of *Health professional* in the Dictionary and also introduces a definition for *immunohaematology reagent IVD medical device* in that dictionary.

Item [95] - Dictionary, after definition of *included in the Register*
This item adds, after the definition of *included in the Register* in the Dictionary, a definition of *in-house IVD medical device*.

Item [96] - Dictionary, after definition of *invasive medical device*
This item adds, after the definition of *invasive medical device* in the Dictionary, definitions of *IVD medical device* and *IVD medical device for self-testing*.

Item [97] – Dictionary, after definition of *kind*
This item adds, after the definition of *kind* in the Dictionary, a definition of *lay person*. This definition is necessary in relation to the definition of *IVD medical device for self-testing,* which refers to lay persons (see item [96] above).

Item [98] – Dictionary, after definition of *medical device used for a special purpose*
This item adds, after the definition of *medical device used for a special purpose* in the Dictionary, a definition of *medical laboratory network*. This definition is necessary in relation to the definition of *in-house IVD medical device,* which refers to medical laboratory network (see item [95]).

Item [99] – Dictionary, after definition of *medicine*
This item adds, after the definition of *medicine* in the Dictionary, a definition of *point of care testing*.

Item [101] – Dictionary, after definition of *reusable surgical instrument*
This item adds, after the definition of *reusable surgical instrument* in the Dictionary, a definition of *sample*. This definition is necessary in relation to the definition of *IVD medical device for self-testing*, which refers to sample (see item [96] above).

Item [102] – Dictionary, definition of *serious*
This item amends the definition of *serious* in the Dictionary by removing reference to "disease" in that definition. That definition currently defines *serious* in relation to a form of a disease, condition, ailment or defect. However, the MD Regulations do not currently refer to *serious* in the context of a disease, so the reference to "disease" in that definition is not needed.

This item, however, also adds a definition of *serious disease* to the Dictionary. This definition is necessary because the term *serious disease* is used in the classification rules for IVD medical devices set out in item [48] above, and has an intended meaning in that context that is specific to IVD medical devices and that is different to the current meaning of the term *serious* in relation to a form of a disease.

The definition of *serious disease* defines that term as a disease that may result in death or long-term disability, may be incurable or require major therapeutic interventions and that must be diagnosed accurately in order to mitigate its public health impact.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2010 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provides that the name of the Regulations is the *Therapeutic Goods Amendment Regulations 2010 (No. 1).*

Regulation 2 – Commencement
This regulation provides that the Regulations commence on 1 July 2010.

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

Regulation 4 – Definitions for transitional provisions
This regulation set out a number of definitions for terms that are mentioned in the transitional arrangements set out in regulations 5, 6 and 7, including definitions for *Act* (being, the *Therapeutic Goods Act 1989*), *in-house IVD medical device* and *IVD medical device*.

Regulation 5 – Transitional – certain devices
This regulation provides, at subregulation 5(1), for transitional arrangements for a diagnostic good for in-vitro use that, immediately before 1 July 2010, was:

(a) declared not to be medical devices under subsection 41BD(3) of the Act; and
(b) (i) registered or listed under Part 3-2 of the Act; or
(ii) subject to an approval under paragraph 19(1)(b) of the Act; or
(iii) exempt from listing or registration under Part 3-2 of the Act; or
(iv) a device for which an effective application for listing or registration had been made but not finally determined.

The effect of subregulation 5(1) is that sponsors of IVD medical devices that are legally supplied under Chapter 3 of the Act before the commencement of the Regulations will be required to apply to include those devices in the Australian Register of Therapeutic Goods (the Register) under Chapter 4 of the Act. These sponsors will have four years to include such devices in the Register under Chapter 4.

Under subregulation 5(2), the listing or registration under Part 3-2 of the Act of an IVD medical device described in paragraphs (b)(i) or (b)(iv) above, are taken to be cancelled on 1 July 2014 if no effective application for including the device in the Register under Chapter 4 of the Act has been made before that date, or on the day when inclusion of the device in the Register under Chapter 4 of the Act takes effect following an effective application for the inclusion of the device in the Register under Chapter 4.

Under subregulation 5(3), notwithstanding the amendments set out in Schedule 1, an IVD medical device that, immediately before 1 July 2010, was exempt from listing or registration under Part 3-2 of the Act, remain exempt until 30 June 2014.

Under subregulation 5(4), the amendments made by Schedule 1 do not apply to an IVD medical device that, immediately before 1 July 2010 was:

- exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A of the Principal Regulations applied to that device; or
- subject to an approval under paragraph 19(1)(b) of the Act; or
- a device for which an application under paragraph 19(1)(b) of the Act had been made but not finally determined.

Subregulation 5(5) defines ***finally determined*** for the purposes of the transitional provisions in regulation 5 as being when the following conditions are met: (a) a decision has been made whether to grant the application and (b) there is no longer the possibility of a change in the outcome of that decision.

Subregulation 5(6) makes it clear that, for the purposes of paragraph 5(6)(b), the possibility of a discretion being exercised by a court or tribunal to extend the period for seeking review of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review, is not to be considered.

Regulation 6 – Transitional – in-house IVD medical devices

This regulation provides that the amendments set out Schedule 1 only apply to in-house IVD medical devices on 1 July 2014. However, sponsors or manufacturers of in-house IVD medical devices may wish to comply with all the relevant requirements applying to in-house IVD medical devices before 1 July 2014. This regulation simply has the effect that all applicable obligations, sanctions and measures under the Act and the Principal Regulations applying to sponsors and manufacturers of in-house IVD medical devices will only be enforced from 1 July 2014.

Regulation 7 – Transitional – other devices

This regulation provides that for IVD medical devices not covered by the scope of regulations 5 or 6 (i.e. IVD medical devices that were not registered or listed on the Register or exempt from registration or listing or the subject of an approval or an application for approval under paragraph 19(1((b) of the Act) the amendments set out in Schedule 1 apply after 30 June 2010.

SCHEDULE 1 – Amendments

Item [1] – Regulation 2, definitions of *active implantable therapeutic device, active therapeutic device, critical medical device, diagnostic goods for in-vitro use* and *goods for home use*

This item omits the definitions of the terms *active implantable therapeutic device, active therapeutic device, critical medical device, diagnostic goods for in-vitro use* and *goods for home use* from regulation 2 of the Principal Regulations. These definitions will no longer be required as these devices will now be regulated as medical devices under the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

Item [2] – Regulation 2, definition of *high level disinfectant*

This item substitutes the current definition of *high level disinfectant* in regulation 2 of the Principal Regulations with a new definition of that term. The effect of this amendment is to remove high level disinfectant intended for use on medical devices from the scope of the definition of *high level disinfectant*. Such disinfectants are now regulated as medical devices under the MD Regulations. The new definition of *high level disinfectant* applies only to high level disinfectants for application to hard surfaces.

Item [3] – Regulation 2, definitions of *implantable*, *instrument grade disinfectant*, *non critical medical device* and *semi critical medical device*

This item omits the definitions of the terms *implantable*, *instrument grade disinfectant*, *non critical medical device* and *semi critical medical device*, from regulation 2 of the Principal Regulations. These definitions will no longer be required, as the medical devices to which they relate will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [4] – Paragraph 3(3)(d)

This item introduces a formatting change to paragraph 3(3)(d) to the reference to the *Therapeutic Goods Act 2001* of Tasmania in that paragraph. This change is necessary in order to accommodate the change described in item [5] below.

Item [5] - After paragraph 3(3)(d)

This item adds, after paragraph 3(3)(d) of the Principal Regulations, a new paragraph 3(3)(e) which refer to the *Medicines, Poisons and Therapeutic Goods Act 2008* of the Australian Capital Territory (the ACT). Regulation 3 of the Principal Regulations sets out State and Territory laws which the *Therapeutic Goods Act 1989* (the Act) permits to confer a function or power, or to impose a duty, on a Commonwealth officer or a Commonwealth authority.

Item [6] – Subregulation 12(1AA)

This item omits subregulation 12(1AA) from the Principal Regulations, which sets out a clarification of the meaning of a powered therapeutic device or part of a therapeutic device for the purposes of item 7 of Schedule 5 of the Principal Regulations. This clarification will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [7] – Regulation 12C

This item omits regulation 12C from the Principal Regulations, which specifies kinds of medical devices to which, under subparagraph 15A(5)(a)(ii) of the Act, Part 3-2 of the Act applies. Regulation 12C will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [8] – Subregulation 15A(1)

This item replaces the reference to the "Drug Safety Evaluation Branch" of the Therapeutic Goods Administration (the TGA) in subregulation 15A(1) of the Principal Regulations with a reference to the "Office of Prescription Medicines" to reflect a change in the name of that branch/office of the TGA.

Item [9] Subregulation 16(2)

This item omits subregulation 16(2) from the Principal Regulations. Subregulation 16(2) prescribes therapeutic devices for the purposes of paragraph 26(1)(g) of the Act (in relation to matters which the Secretary may consider warrant a refusal to list a product under section 26 of the Act). Subregulation 16(2) will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [10] – Regulation 46A

This item introduces a formatting change to regulation 46A of the Principal Regulations by setting out that the current wording of regulation 46A is subregulation 46A(1). This change is necessary in order to accommodate the change described in item [11] below.

Item [11] – After regulation 46A

This item adds a new subregulation 46A(2) in the Principal Regulations to prescribe, for the purposes of paragraph 57(8)(b) of the Act, the Chief Regulatory Officer and the Principal Medical Adviser. Under paragraph 57(8)(b) of the Act, the powers of the Secretary under section 19A of the Act (regarding exempting therapeutic goods due to unavailability or short supply) may be delegated to a person who holds, occupies or performs the duties of a position in the TGA prescribed by the regulations for the purposes of that paragraph.

Item [12] – Schedule 3, Part 1, item 3, paragraphs (a), (b), (c), (d), (e) and (f)

This item omits paragraphs (a) to (f) of item 3 of Part 1 of Schedule 3 to the Principal Regulations. Those paragraphs relate to specified kinds of therapeutic devices such as implantable intra-ocular lenses and intra-uterine contraceptive devices. These devices will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [13] - Schedule 3, Part 1, item 3, paragraph (g)

This item replaces the current paragraph (g) of item 3 of Part 1 of Schedule 3 to the Principal Regulations with a new paragraph (g) of that item. The effect of this amendment is to clarify that only therapeutic devices that are articles incorporating material of human origin (with the exception of stable derivatives of human blood or plasma that act or are likely to act on the human body in a manner ancillary to the medical device with which they are associated), and viable materials of animal origin, will continue to be regulated by the Principal Regulations as registered therapeutic devices.

Item [14] Schedule 3, Part 1, item 3, paragraph (h)

This item omit paragraph (h) of item 3 of Part 1 of Schedule 3 to the Principal Regulations. Paragraph (h) of item 3 refers to implantable breast prostheses consisting of, or containing, material of fluid consistency that is other than only water or a saline solution, if unintentional migration of that material to a part of the body away from the site of implantation could occur. Paragraph (h) of item 2 will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [15] – Schedule 3, Part 1, items 4 and 5

This item omit items 4 and 5 from Part 1 of Schedule 3 to the Principal Regulations. Items 4 and 5 refer to a number of therapeutic devices such as auditory nerve stimulators and implantable therapeutic devices that incorporate an ancillary medicinal substance. Items 4 and 5 will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [16] – Schedule 3, Part 2, items 2, 3, 4, 5, 7 and 8

This item omits items 2 to 5 and 7 to 8 from Part 2 of Schedule 3 to the Principal Regulations. These items refer to a number of therapeutic devices such as instrument grade disinfectants and sterilants claimed to be fungicides, sporicides, tuberculocides or virucides that are intended by the manufacturer to be used on a critical or semi-critical medical device, and control materials for use with IVD medical devices. These items will no longer be required as such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [17] – Schedule 4, Part 1, item 2, paragraph (a)

This item replaces the current paragraph (a) of item 2 of Part 1 of Schedule 4 to the Principal Regulations with a new paragraph (a). This amendment has the effect of removing references in that paragraph to therapeutic devices which are to be omitted from Schedule 3 by the Regulations (see items [12], [14] and [15]) and which will now regulated as medical devices

under Chapter 4 of the Act, and the MD Regulations. The new wording of paragraph (a) of item 2 retains a modified reference to products that continues to be regulated under Chapter 3 of the Act as registered therapeutic devices.

Item [18] – Schedule 4, Part 1, item 2, paragraph (b)

This item replaces the current paragraph (b) of item 2 of Part 1 of Schedule 4 to the Principal Regulations with a new paragraph (b), with the effect of removing references in that paragraph to therapeutic devices which is omitted from Schedule 5 to the Principal Regulations by the Regulations (see items [20], [21] and [23]) and which will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations. The new wording of paragraph (b) of item 2 retains a modified reference to products that continues to be regulated under Chapter 3 of the Act as therapeutic devices.

Item [19] – Schedule 4, Part 1, items 13, 14 and 15

This item omits items 13, 14 and 15 from Part 1 of Schedule 4 to the Principal Regulations. These items refer to a number of therapeutic devices, such as certain kinds of intra-ocular lenses and non-powered endoscopes and endoscopic accessories. Items 13, 14 and 15 will no longer be required as these devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [20] – Schedule 5, item 5

This item omits item 5 from Schedule 5 to the Principal Regulations. Item 5 refers to certain custom-made therapeutic devices. Item 5 will no longer be required as these devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [21] – Schedule 5, item 7, paragraphs (a), (b), (c) and (d)

This item omits paragraphs (a) to (d) of item 7 of Schedule 5 to the Principal Regulations. These paragraphs refer to therapeutic devices and parts of therapeutic devices that will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations and, as such, paragraphs (a) to (d) of item 7 will no longer be required.

Item [22] – Schedule 5, item 7, paragraph (e)

This item replaces the current paragraph (e) of item 7 of Schedule 5 to the Principal Regulations with a new paragraph (e). This amendment has the effect of removing references in that paragraph to manufacturing, laboratory and dispensary equipment used in diagnosis which will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations. The new wording of paragraph (e) maintains the exemption from the operation of Part 3-2 of the Act for manufacturing, laboratory and dispensary equipment used in the preparation of therapeutic goods.

Item [23] – Schedule 5, item 7, paragraphs (f) – (p)

This item omits paragraphs (f) to (p) of item 7 of Schedule 5 to the Principal Regulations. These paragraphs refer to a number of therapeutic devices, such as dental impression materials and non-powered hot or cold packs. Paragraphs (f) to (p) of item 7 will no longer be required as these devices will now be regulated as medical devices under Chapter 4 of the Act and the MD Regulations.

Item [24] – Schedule 5, item 8, subparagraph (f)(i)

This item modifies subparagraph (f)(i) of item 8 of Schedule 5 to the Principal Regulations to omit reference in that subparagraph to therapeutic devices described in item 5 of Part 2 of Schedule 3 to the Principal Regulations. Such devices will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations and, as such, the reference in

subparagraph (f)(i) will no longer be required. The new wording of subparagraph (f)(i) of item 8 continues to refer to those products described under item 6 of Part 2 of Schedule 3 which will continue to be regulated under Chapter 3 of the Act and to be exempt from the operation of Part 3-2 of the Act.

Item [25] – Schedule 5, item 8, subparagraph (f)(ii)

This item introduces a formatting change to subparagraph (f)(ii) of item 8 of Schedule 5 to the Principal Regulations, by removing the reference to "or" after the semi-colon in that subparagraph. This change is necessary as item [26] below, omits subparagraph (f)(iii) of item 8 of Schedule 5.

Item [26] – Schedule 5, item 8, subparagraph (f)(iii)

This item omits subparagraph (f)(iii) from item 8 of Schedule 5 to the Principal Regulations. Subparagraph (f)(iii) of item 8 refers to disinfectants except disinfectants for use with contact lenses. As such products will now be regulated under Chapter 4 of the Act, and the MD Regulations, subparagraph (f)(iii) will no longer be required.

tem [27] – Schedule 5A, item 7

This item replaces the current wording of item 7 of Schedule 5A to the Principal Regulations with a new item 7, with the effect of removing references in that item to therapeutic goods or parts of therapeutic goods that form part of device kits specified in the current item 7. Such products will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations. As such, references to those products in item 7 of Schedule 5A will no longer be required. The new wording of item 7 of Schedule 5A maintains and clarifies the existing exemption from the operation of Part 3-2 of the Act for device components of a medicine delivery system in which the medicine is supplied in a device that acts as a container for the medicine. Such products continue to be regulated under Chapter 3 of the Act.

Item [28] – Schedule 6, items 3, 3A and 4

This item omits items 3.3A and 4 from Schedule 6 to the Principal Regulations. Items 3.3A and 4 refer to a number of therapeutic devices (respectively, non-sterile preserved multi-gel wound dressings (hydrogel), and certain kinds of containers) which will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations. As such, items 3.3A and 4 of Schedule 6 will no longer be required.

Item [29] – Schedule 7, items 3, 4 and 5

This item omits items 3, 4 and 5 from Schedule 7 to the Principal Regulations. Items 3, 4 and 5 of Schedule 7 refer to a number of therapeutic devices, components for therapeutic devices, therapeutic devices that are not sterile and do not contain or include any sterile component or portion other than specified components or portions and certain kinds of containers. Items 3, 4 and 5 will no longer be required as these therapeutic devices will be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations.

Item [30] – Schedule 7, item 13

This item substitutes a new item 13 for the current item 13 of Schedule 7 to the Principal Regulations to remove reference to instrument grade disinfectants, which will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations. The new wording of item 13 of Schedule 7 has the effect that hospital, household and commercial grade disinfectants continue to be regulated under Chapter 3 of the Act and be exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits under the *National Health Act 1953* or the *Veterans' Entitlements Act 1986*.

Item [31] – Schedule 9, Part 2, after item 2A
This item sadd to Schedule 9 to the Principal Regulations, after item 2A of that schedule, an application fee that applies in the event a sponsor of a kind of IVD medical device requests that the Secretary vary the entry in the Register relating to that device. The fee is $340.

Item [32] – Schedule 10, Part 1, heading
This item replaces the heading of Part 1 of Schedule 10 to the Principal Regulations to replace the reference in that heading to the "Drug Safety Evaluation Branch" with a reference to the "Office of Prescription Medicines" to reflect a change in the name of that branch/office of the TGA.

Item [33] – Schedule 10, Part 1, item 14
This item replaces the reference to "Drug Safety Evaluation Branch" in column 2 of item 14 of Schedule 10 to the Principal Regulations with a reference to "Office of Prescription Medicines" to reflect a change in the name of that branch/office of the TGA.

Item [34] – Schedule 10, Part 1, item 16
This item omits item 16 from Schedule 10 to the Principal Regulations. Item 16 of Schedule 10 refers to a therapeutic device that depends upon the release of a substance for some or all of its action. Such a device will now be regulated as a medical device under Chapter 4 of the Act, and the MD Regulations and, as such, item 16 will no longer be required.

Item [35] – Schedule 10, Part 2, item 3
This item replaces the reference to "Complementary Medicines Section" in column 2 of item 3 of Schedule 10 to the Principal Regulations with a reference to "Office of Complementary Medicines" to reflect a change in the name of that section/office of the TGA.

Item [36] – Schedule 10, Part 3, heading
This item replaces the current heading of Part 3 of Schedule 10 to the Principal Regulations to remove the reference to "OTC Medicine Evaluation Section of the Department" and add instead a reference to "Office of Non-Prescription Medicines" to reflect a change in the name of the area within the TGA which is responsible for evaluating the therapeutic goods mentioned in Part 3 of Schedule 10.

tem [37] – Schedule 10, Part 3, item 5
This item amends column 2 of item 5 of Part 3 of Schedule 10 to the Principal Regulations to replace the reference in column 2 of that item to the "Scheduling and Over-the-counter Drug Evaluation Section" of the TGA with a reference to the "Office of Non-Prescription Medicines" to reflect a change in the name of the area within the TGA which should be referred to in column 2 of item 5.

Item [38] – Schedule 11
This item omits Schedule 11 from the Principal Regulations. Schedule 11 sets out therapeutic goods for which quality or safety criteria are prescribed for the purposes of paragraph 6(1)(k) of the Act. These goods will now be regulated as medical devices under Chapter 4 of the Act, and the MD Regulations, and as such Schedule 11 will no longer be required.