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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

**HOUSE OF REPRESENTATIVES**

**THERAPEUTIC GOODS AMENDMENT (2017 MEASURES NO. 1) BILL 2017**

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Minister for Sport, the Honourable Greg Hunt MP)

## **THERAPEUTIC GOODS AMENDMENT (2016 MEASURES NO. 1) BILL 2017**

### **OUTLINE**

The Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 (the Bill) makes a number of amendments to the *Therapeutic Goods Act 1989* (the Act).

These amendments will:

- a) support the implementation of a number of important recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review);
- b) provide clarity regarding issues raised in relation to the processing of applications by the Therapeutic Goods Administration (the TGA) within the Department of Health by the Federal Court's decision in *Nicovations Australia Pty Ltd v Secretary of the Department of Health* [2016] FCA 394 (*Nicovations*); and
- c) make a number of miscellaneous amendments to the Act, principally aimed at ensuring greater consistency across the regulation of different kinds of therapeutic goods.

### ***Second stage of legislative response to the Review of Medicines and Medical Devices Regulation***

The Review was undertaken to identify unnecessary or ineffective regulation and propose opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods. The Government response to the report was released in September 2016.

The *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*, which received Royal Assent on 19 June 2017 and commenced (in most part) on 20 June 2017, supported the implementation of eight key recommendations of the Review (Review recommendations 3, 13, 15, 24, 27, 41, 42 and 47).

This Bill supports the implementation of further key Review recommendations, including in particular the introduction of a scheme for the granting of provisional marketing approval of medicines, reforms to the advertising of therapeutic goods, changes to the regulation of complementary medicines, and streamlined sanctions and penalties under the Act. Further amendments in the Bill align the provisions in the Act relating to biologicals with Review-related changes for medicines and medical devices.

### ***Provisional registration of promising new prescription medicines***

The Review recommended that a new approval pathway for new prescription medicines be established using early clinical data, to allow faster approval and availability of promising new medicines (Review recommendations 3 and 10).

The Bill supports the implementation of these recommendations by creating a new class of therapeutic goods to be registered on the Australian Register of Therapeutic Goods (Register), to be known as ‘provisionally registered goods’.

The ‘Provisional Approval’ pathway will provide earlier access to certain promising new medicines that do not yet have a full dossier of data (in particular clinical data), where there is the potential for a substantial benefit to Australian consumers through the earlier availability of these medicines.

This pathway will allow sponsors to apply for a time-limited provisional registration of certain prescription medicines on the basis of promising early clinical data on efficacy and safety having been reviewed and accepted by the TGA within the Department of Health.

Sponsors will be required to fulfil post-market conditions to confirm the efficacy and safety of their medicine, and to communicate with health professionals and patients about the risks inherent in the fact that additional clinical data will not yet be available in relation to these products.

The provisional registration of new medicines will be a two-stage process:

- sponsors will be required to submit a determination application for the Provisional Approval pathway to determine whether the medicine meets eligibility criteria; and
- where successful in being granted a provisional determination, sponsors will submit a Provisional Approval registration application and supporting dossier for assessment by the Secretary.

The Bill provides for the Secretary to make a provisional determination which, if granted, will act as a gateway to entry to the application and evaluation process for provisional registration.

The Bill includes new provisions under which goods may be evaluated for provisional registration. It also limits the provisional registration period to two years and enables a sponsor to make an application to the Secretary for the extension of the provisional registration period by one or two years, with a maximum of two such extensions available.

A sponsor may also make a formal application for the full registration of a provisionally registered medicine, which will involve a more abbreviated process than a full evaluation under s 25 of the Act.

#### *Reforms to the regulatory framework for complementary medicines*

- a. Establishing a list of permitted indications for listed complementary medicines*

The Review recommended that a list of Permitted Indications be established for listed complementary medicines, from which sponsors of these products must exclusively draw, when applying to list their medicines in the Australian Register of Therapeutic Goods (the Register) (Review recommendation 38). An indication is a statement of a specific therapeutic use for a medicine, i.e. a statement relating to the use of the product to treat a particular condition.

The Bill implements this recommendation by, in particular, providing the Minister with a power to make a legislative instrument specifying permitted indications for use with listed medicines. Sponsors will be required, when applying to list their medicines in the Register, to certify that each indication for their medicine is permitted under the new instrument, and it will be a ground for cancellation from the Register if such a certification was, or is no longer, correct.

This will ensure that listed medicines may only make pre-approved, low level claims for the conditions that the medicine can treat, which are appropriate for medicines that are not assessed prior to accessing the market.

*b. Establishing a new assessment pathway for listed complementary medicines*

The Review recommended that there be three risk-based pathways available for inclusion of complementary medicines in the Register (Review recommendation 39).

At present, listed complementary medicines are included in the Register on the basis of self-certification by the applicant, while the registration of complementary medicines requires evaluation by the TGA.

The Bill implements this recommendation by establishing an additional pathway for intermediate risk medicines. This pathway consists of a new application and assessment process for sponsors of listed complementary medicines seeking to use indications that fall outside the permitted indications list.

The amendments will allow these medicines to be included in the Register following certification by the sponsor about the safety and quality of the product, and assessment by the Secretary of the efficacy evidence supporting the proposed indications.

*c. Allowing sponsors to claim evidence of efficacy*

The Review recommended that where a product is listed on the Register following an assessment of its efficacy by the Secretary, the sponsor be able to indicate on all promotional materials and on the product label that the efficacy of the product has been independently assessed for the approved indication(s) (Review recommendation 45).

The Bill implements this recommendation by authorising sponsors of relevant products to use a 'claimer' (defined as words or phrases that make a claim about a condition which a product

can be used to treat) on the packaging and advertising for listed complementary medicines that have been evaluated by the TGA through this process.

#### *Developing a more comprehensive post-market monitoring scheme*

The Review recommended that a more comprehensive post-market monitoring scheme be developed to enhance consumer protection and complement existing post-market processes (Review recommendation 27).

The Bill supports the implementation of this recommendation by strengthening the monitoring powers in relation to biologicals, making changes similar to those made in relation to medicines in the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*.

These amendments add compliance with record-keeping requirements to the standard conditions of registration for biologicals, enable the inspection of premises where documents are kept in relation to biologicals, and enable record-keeping requirements for biologicals to be prescribed in the regulations.

#### *Broadening investigation and enforcement powers*

The Review recommended that consideration be given as to whether the current range of investigation and enforcement powers under the Act should be broadened (Review recommendation 57). The Review further suggested that a comprehensive review of the legislative framework for therapeutic goods be undertaken (Review recommendation 28). The Bill supports these recommendations by implementing stronger compliance and enforcement powers to protect the public, and by providing for graduated penalties that allow the TGA to respond appropriately to the full range of non-compliant behaviours.

The amendments incorporate into the Act a number of powers from the *Regulatory Powers (Standard Provisions) Act 2014* (the Regulatory Powers Act), with some modifications. This will bring the powers of the Secretary in relation to monitoring, investigation, infringement notices and injunctions, into line with those of comparable Commonwealth regulators (including the Australian Sports Anti-Doping Authority within the Health portfolio, and the Office of Drug Control and the National Industrial Chemicals Notification and Assessment Scheme in the Department of Health).

The proposed changes will also remove the current requirement to prove harm, or the likelihood of harm, from strict liability offences in the Act, and reduce the maximum penalties for these offences. Aggravated criminal offences in the Act will be strengthened by including the likelihood of harm or injury, to better address culpable behaviour. Strict liability offence provisions will complement, where appropriate, existing 'stand-alone' criminal offences throughout the Act for matters such as breaches of conditions, licences or permits. Existing offences in relation to advertising of therapeutic goods will be strengthened and clarified to deter inappropriate and misleading advertising of therapeutic goods.

#### *Advertising requirements*

The Review recommended that the advertising of therapeutic products to the public continues to be regulated by the Secretary under a legislative framework that includes an advertising code (Review recommendation 52). The Review further recommended that the process of vetting and pre-approval of the advertising of therapeutic products to the public should cease and the handling of advertising complaints should be the responsibility of a single agency (Review recommendations 55 and 56).

The Review recommended that future requirements for advertising therapeutic goods to the public be consistent for all medicines and medical devices, and that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime (Review recommendations 54 and 55).

The Bill supports the implementation of these recommendations by removing the distinctions in the Act between advertisements for therapeutic goods for which an approval is, or is not, required, with effect from 1 July 2018.

The Review also recommended that consideration be given as to whether the current range of investigation and enforcement powers should be broadened (Recommendation 57). The Government response to the Review noted that implementing Recommendation 57 is critical for managing potential concerns by consumers and healthcare professionals in accepting Recommendation 55.

The Bill supports this recommendation by broadening the enforcement options available to deal with breaches of advertising requirements.

#### *Enabling greater use of assessments of comparable overseas regulators*

The Review recommended that the TGA make greater use of assessments from comparable overseas regulators in assessing medicines and medical devices, while continuing to be responsible for final regulatory decisions (Review recommendations 15 and 17).

The Bill supports the implementation of these recommendations by making amendments to enable the Secretary to utilise the work of comparable overseas regulators in making its own assessments of medical devices (similar amendments to the Act are not needed to enable the use of overseas reports in evaluating medicines, as this is already compatible with the relevant provisions in the Act relating to those products).

In particular, the amendments require an applicant for the inclusion of a kind of medical device in the Register to certify that an appropriate conformity assessment procedure, or an equivalent procedure carried out by a comparable overseas regulator, has been carried out in relation to medical devices of that kind. The relevant overseas regulators would be specified in a legislative instrument.

#### *Recognising Australian conformity assessment bodies*

The Review recommended that legislative provision be made for the recognition of Australian conformity assessment bodies (Review recommendations 15 and 16).

The *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017* made most of the legislative changes required to enable the TGA to authorise Australian companies to undertake conformity assessments. This Bill contains some refinements to that new scheme, to enable the Secretary to publish information in relation to Australian conformity assessment bodies and to ensure that the Secretary has the same powers in relation to conformity assessment certificates issued by Australian conformity assessment bodies as it does in relation to EU or conformity assessment certificates issued by the Secretary.

#### *Amendments clarifying the TGA's pre-assessment process*

The Bill amends the application provisions in the Act to clarify that the Secretary has the power to refuse an application prior to evaluation, where the application does not meet the requirements for an application; for example, in relation to an application to register a therapeutic good such as a prescription medicine, that the application has been made on the form approved in writing by the Secretary for prescription medicines and that the application is accompanied by specified information. The clarifications are in response to the decision of the Federal Court in *Nicovations Australia Pty Ltd v Secretary Department of Health* [2016] FCA 394

#### *Amendments to achieve consistency between types of therapeutic goods and other minor changes*

The following minor amendments are intended to achieve consistency between different types of therapeutic goods and to make minor changes to the Act to:

##### *Consequential Review measures*

- ensure the consistent treatment of biologicals with other therapeutic goods supplied under the new notification-only part of the Special Access Scheme for category B patients, by exempting the lawful supply of unregistered biologicals under that scheme from the offences in the Act for supplying, using, advertising, and making misrepresentations about a biological;
- ensure consistent grounds for suspension and cancellation of registration or listing of therapeutic goods with the grounds for suspension or cancellation of biologicals and medical devices by providing for suspension of the registration or listing of goods where the Secretary is satisfied that the sponsor provided false information in the application for registration or listing; and
- more precisely define the authority under which searches of premises to monitor compliance with the Act may be undertaken.

##### *Achieving greater consistency*

- ensure that the requirement to provide samples to the Secretary on request that currently applies as a condition of registration for medical devices, biologicals and listed complementary medicines also applies to registered medicines;

- ensure that the grounds for suspending a biological or medical device from the Register are consistent with the suspension grounds for medicines, by removing the non-payment of annual charges as a ground for suspending devices and biologicals (a new procedure for reinstating goods that were cancelled for non-payment has been introduced, that makes suspension on this grounds unnecessary);
- for consistency with the regulation of medicines, ensure that the civil penalty for exporting a medical device that does not comply with the essential principles does not apply where the variation from the essential principles is that it is not labelled for supply in Australia;
- expand the category of medical devices which may be distributed under the Authorised Prescriber and Special Access Schemes to encompass devices used for diagnosis or monitoring. Currently the Act only exempts from devices from inclusion in the Register in relation to these schemes if the devices are used in the treatment of patients

#### Other minor amendments

- enable the Secretary to vary a multi-site manufacturing licence to remove a manufacturing site from the licence if the licence-holder requests this. Currently there is a power to vary a multi-site licence to add a new site to the licence (s40B(1)), but not to remove a site from the licence;
- require that, if a medicine that was registered without product information is re-scheduled so that it becomes a restricted medicine, product information must be provided to the Secretary. Currently, there is no mechanism to require the provision of product information for medicines that are up-scheduled after they are registered (such as codeine); and
- enable the Secretary to request samples of medical devices when they are selected for audit. Samples of devices must be provided on request once a device is included in the Register (s41FN(2)), but there is currently no power to request samples of a device when the device is being audited prior to inclusion.

### **Financial Impact Statement**

The Government allocated \$13.5 million in both operating and capital expenses from the Budget in 2016-2017 to improve the regulation of therapeutic goods in Australia. The TGA special account reserves (comprised of revenue from industry fees and charges) will be used to fund this allocation.

### **Regulation Impact Statement**

A Regulation Impact Statement (RIS) is not required for the Review-related proposals described above. The Deputy Secretary of Strategic Policy and Innovation Group of the Department wrote to the Office of Best Practice Regulation (OBPR) certifying that the Review undertook a process and analysis similar to that required for a RIS. The process is in line with Best Practice Regulation requirements as set out in the *Australian Government Guide to Regulation*. Regulatory costings have been agreed by OBPR (OBPR ID 18884).



Additionally, the Department has been advised by OBPR that no RIS is required in relation to the non-review amendments (reference nos. 21178 and 22289). A RIS was published on 13 February 2017 in relation to the re-scheduling of codeine (OBPR ID number 19826) which dealt with the proposed changes to requirements to provide product information.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### **THERAPEUTIC GOODS AMENDMENT (2017 MEASURES NO. 1) BILL 2017**

The Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 (the Bill) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Bill**

This Bill amends the *Therapeutic Goods Act 1989* (the Act) in relation to a range of matters, including in particular to support the implementation of a number of recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review). The Review was undertaken to identify unnecessary or ineffective regulation and propose opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods. The Government response to the report was released in September 2016.

The *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017* supported the implementation of eight key recommendations of the Review (Review recommendations 3, 13, 15, 24, 27, 41, 42 and 47). This Bill supports the implementation of further key recommendations, including amendments to the Act to:

- provide for a scheme for the provisional registration of promising new prescription medicines;
- reform the regulatory framework for complementary medicines;
- implement stronger compliance and enforcement powers to protect the public from behaviour that breaches the Act, and provide for graduated penalties that allow the Secretary to respond appropriately to the full range of non-compliant behaviours;
- provide for reforms to the advertising of therapeutic goods;
- enable the Secretary to make greater use of assessments from comparable overseas regulators in assessing medicines and medical devices; and
- recognise more broadly the intended role of Australian conformity assessment bodies.

In addition, the Bill seeks to address issues raised by the Federal Court's decision in the matter of *Nicovations Australia Pty Ltd v Secretary of the Department of Health* [2016] FCA 394 (*Nicovations*) in relation to the processing of applications for registration, listing and inclusion by the TGA.

The Bill also makes a number of miscellaneous amendments to the Act, principally to achieve greater consistency in the regulation of different kinds of therapeutic goods, make minor amendments that are consequential to the implementation of the Review measures, and a small number of other minor changes such as enabling the Secretary to request samples of a medical device when sponsors apply to include devices in the Register.

#### **Human rights implications**

##### *List of human rights*

The Bill engages, or has the potential to engage, the following human rights:

- right to health - Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR);
- right to work – Article 6 of the ICESCR;
- right to privacy and reputation – Article 7 of the International Covenant on Civil and Political Rights (the ICCPR);
- right to a fair trial/fair hearing - Article 14 of the ICCPR;
- right to freedom of movement – Article 12 of the ICCPR;
- right to the presumption of innocence - Article 14 (2) of the ICCPR;
- right to be free from self-incrimination - Article 14(3) of the ICCPR;
- right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted - Article 14 (7) of the ICCPR;
- right to freedom of association - Article 22 of the ICCPR;
- right to freedom from torture and cruel, inhuman or degrading treatment – Articles 7 and 10 of the ICCPR;
- right to liberty and freedom from arbitrary detention – Article 9 of the ICCPR.

## **Assessment of compatibility with human rights**

### *Right to health*

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. This includes the application of measures for the prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)). While the UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee has stated that the notion of ‘the highest attainable standard of health’ takes into account both the conditions of the individual and the country’s available resources. The right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs and conditions necessary for the realisation of the highest attainable standard of health.

The Bill takes positive steps to promote this right by, in particular the:

- inclusion of the new ‘Provisional Approval’ pathway – see Schedule 1
- inclusion of the new permitted indications list and the new assessment pathway to list medicines
- more streamlined enforcement measures to support a robust regulatory framework

### *Right to privacy and reputation*

Article 17 of the ICCPR provides for the right not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with an individual's privacy, family, home and correspondence. It also protects a person's honour and reputation from unlawful attacks.

This right may be subject to permissible limitations where those limitations are provided by law and are non-arbitrary. In order for limitations not to be arbitrary, they must be aimed at a legitimate objective and be reasonable, necessary and proportionate to that objective.

Chapter X of the Bill provides for compliance and enforcement powers, including powers to be drawn from the Regulatory Powers Act.

### Powers of monitoring and inspection

The Bill allows authorised persons to monitor and inspect premises which may be considered to form part of a person's home or workplace within the scope of Article 17.

The Bill inserts provisions modelled on the Regulatory Powers Act with the following modifications:

- the monitoring and investigation powers in the Regulatory Powers Act are modified to maintain the existing 'sampling' powers of authorised officers;
- the additional powers in relation to entering and searching premises set out in existing sections 46A and 46B of the Act are retained;
- the power in existing section 51A relating to searches at the request of a manufacturer is also retained.

Schedule 7 of the Bill replaces the powers relating to entry, searches and warrants set out in existing Part 6-2 of the Act, with similar powers adopted from the Regulatory Powers Act. The new monitoring and investigation powers include the ability to search the premises, inspect documents or things on the premises, take extracts or copies of documents and sample anything on the premises. Additional powers available include the powers to seize evidence and ask questions and seek production of documents.

These powers are necessary for the legitimate objective of ensuring that relevant information required under the Act and information required to assess compliance with the Act, is accessible and available to officers when required. However, these clauses may operate to limit the right to privacy as they enable entry to premises that may be a person's residence and inspection, copying and sampling of potentially personal information.

### *Right to the presumption of innocence*

Article 14(2) of the ICCPR states that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to presumption of innocence is also a fundamental common law principle.

When ‘strict liability’ applies to an offence, the prosecution is only required to prove the physical elements of an offence, not the fault elements, beyond reasonable doubt in order for the defendant to be found guilty. The defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the Criminal Code).

Strict liability is used in circumstances where there is public interest in ensuring that regulatory schemes are observed and it can reasonably be expected that the person was aware of their duties and obligations. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault.

Strict liability offences will not necessarily be inconsistent with the presumption of innocence provided that removal of the presumption of innocence pursues a legitimate objective and is reasonable, necessary and proportionate to achieving that objective. Whether a strict liability provision impermissibly limits the right to the presumption of innocence will depend on the circumstances of the case and the particular justification for an offence being a strict liability offence.

### *Right to a fair hearing and fair trial*

Article 14 of the ICCPR provides for the right to a fair and public criminal trial or a public hearing in civil proceedings. Fair trial and fair hearing rights provide that all persons are equal before courts and tribunals, and have the right to a fair and public hearing before a competent, independent and impartial court or tribunal established by law.

The right is concerned with procedural fairness, rather than with the substantive decision of a court or tribunal. What constitutes a fair hearing will require recognition of the interests of all parties in a civil proceeding. The procedures followed in a hearing should respect the principle of ‘equality of arms’, which requires that all parties to a proceeding must have a reasonable opportunity of presenting their case under conditions that do not disadvantage them as against other parties to the proceedings.

### Infringement notices

The Bill engages the right to a fair and public hearing through the replacement of the current infringement notice scheme with that under Part 5 of the Regulatory Powers Act. Under the amendments in Schedule 7, an infringement notice can be issued by an infringement officer for contraventions of a strict liability offence provision or a civil penalty provision.

The right of a person to a fair and public hearing by a competent, independent and impartial tribunal is preserved by the Bill as a person may elect to have the matter heard by a court rather than pay the amount specified in the notice. The Bill also specifies the requirements for what must be included in an infringement notice, ensuring that a person issued with an infringement notice is aware of their right to have the matter heard by a court. As the person may elect to have the matter heard by a court, rather than pay the penalty, the right to a fair hearing in civil matters provided for by Article 14(1) of the ICCPR is engaged but not limited.

### Penalty levels in new civil penalty provisions

The Bill introduces some new civil penalty provisions that have a maximum penalty level of 50,000 penalty units for a body corporate (and 5,000 penalty units for an individual):

The Parliamentary Joint Committee on Human Rights has, in the past, sought further information on provisions of this nature and whether they may be regarded as ‘criminal’ for the purposes of international human rights law (having regard to the Committee’s Guidance Note 2) and, if so, whether the provisions accord with the right to a fair trial.

In each case, these provisions are clearly identified in the Bill as being a civil penalty, and are plainly distinguishable as such from the corresponding criminal offences relating to the same conduct.

Although the maximum levels of these penalties may appear high, this is designed to reflect the size and nature of the therapeutic goods industry, and the significant health dangers that major problems with medicines, biologicals and medical devices can cause to patients.

The maximum penalty levels for these new civil penalty provisions are also consistent with the regime throughout the Act of having civil penalties as an alternative to criminal offences for a range of behaviour that breaches important regulatory requirements. For example, section 9H of the Act (which the Committee considered in its Second Report of the 44<sup>th</sup> Parliament) sets out a civil penalty provision for making false statements in, or in connection with, a request to vary an entry for a therapeutic good in the Register, with identical maximum penalty levels to the proposed new sections outlined above. Similarly, new section 41AF of the Act, introduced by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (which the Committee considered in its Fourth Report of 2017), also has the same maximum penalty level in relation to the provision of false or misleading information by a therapeutic goods manufacturer.

It is also important to note that the new civil penalty provisions that would be introduced by the Bill would not apply to the public in general, but would only arise in the specific regulatory context of therapeutic goods.

In addition, these new civil penalty provisions do not carry any sanction of imprisonment for non-payment. Section 42YD of the Act makes it clear that if the Federal Court orders a person to pay a civil penalty, the Commonwealth may enforce the order as if it were a judgment of the Court, that is, as a debt owed to the Commonwealth.

With these points in mind, the above civil penalty provisions would not seem likely to be ‘criminal’ for the purposes of international human rights law and, accordingly, any question as to whether they would be consistent with the right to a fair trial would not appear to arise.

The Act also protects a person from being required to pay a civil penalty if they have already been convicted of an offence relating to the same conduct, and prohibits criminal proceedings from being started if an order has been made against the person in civil penalty proceedings for the same conduct. Any civil penalty proceedings will be stayed if criminal proceedings relating to the same conduct are, or already have been, started. In addition, the Act also

makes it clear that any evidence given by a person in civil penalty proceedings (whether or not any order was made by the Court in those proceedings) will not be admissible in criminal proceedings involving the same conduct.

### Injunctions

Under the amendments in Schedule 7 to this Bill, an injunction can be granted in relation to contraventions of the offence and civil penalty provisions of the Act.

The injunction provisions engage the right to a fair and public hearing and the other criminal process rights and minimum guarantees in Article 14 of the ICCPR.

Under Part 7 of the Regulatory Powers Act, an injunction can only be granted by a court. Further, a court may only grant an injunction where a person has engaged, is engaging or is proposing to engage, in conduct that contravenes a provision of the Act, or where a person has refused or failed, or is refusing or failing, or proposing to refuse or fail, to do a thing and that refusal or failure was, is or would be a contravention of a provision of the Act. Thus, the right to a fair and public hearing by a competent, independent and impartial tribunal is not limited.

The other criminal process rights and minimum guarantees in Article 14 of the ICCPR are not limited by the amendments in Schedule 7.

### **Conclusion**

The Bill is compatible with the human rights outlined above because it promotes the protection of human rights and to the extent that it may operate to limit these rights, the limitations are reasonable, necessary and proportionate to achieve legitimate objective

**The Honourable Greg Hunt MP, the Minister for Health and Minister for Sport**

## NOTES ON CLAUSES

### **Clause 1 – Short Title**

This clause provides that the Bill, once enacted may be cited as the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2017*.

### **Clause 2 – Commencement**

This clause sets out the manner in which the provisions in the Bill will commence. Sections 1 to 3 commence on the day that the Bill receives Royal Assent. Schedules 1, 2, 4, Part 2 of Schedule 6 and Schedule 8 commence on the later of 1 January 2018 or the day after the Act receives Royal Assent. The commencement of the balance of the Schedules is contingent on the commencement of other Schedules: Schedule 3 commences immediately after the commencement of Schedules 1 and 2; Part 1 of Schedule 6 and Schedule 7 commence immediately after the commencement of Schedules 4 and 5; and Schedule 9 commences immediately after the commencement of Part 1 of Schedule 6.

### **Clause 3 – Schedule(s)**

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms.



## **SCHEDULE 1: Provisional registration of medicine**

### ***Therapeutic Goods Act 1989***

This Schedule establishes a scheme for the registration of medicine via what is known as the ‘Provisional Approval’ pathway to registration.

The Provisional Approval pathway will allow medicines to be available to patients with significant unmet clinical needs for serious conditions earlier than might otherwise be the case. It allows medicines to be available under strict conditions where there is highly promising but preliminary efficacy data and where no major safety concerns have been identified. For example, new cancer medicines may be available to the public up to two years earlier than under the current regulatory scheme. Full non-clinical modules (e.g. quality, manufacturing and toxicology) would still be required in the submission. This would allow for the Department (through the TGA) to provide provisional registration of a medicine in the Register, in the absence of full Phase III trial safety and efficacy data, where the benefit to public health of the immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required.

The registration decision will take into account whether there is sufficient evidence that the benefit-risk balance is positive; there is promising evidence that early availability of the medicine will provide a significant benefit to Australian patients with unmet clinical needs and that the sponsor has demonstrated capacity to submit comprehensive clinical data on efficacy and safety within the timeframes of provisional registration. Similar schemes have been in place in Europe and North America for some years.

Provisional registration for marketing in Australia will be limited in duration. The sponsor will also be required to meet conditions imposed by the Department (through the TGA). For example, a requirement could be to provide post market efficacy and safety data within a given timeframe to substantiate subsequent ongoing approval. When enough data on the medicine are provided to confirm adequate safety and efficacy standards, the sponsor could apply for the medicine to receive ‘full’ registration. If the required data cannot be provided within the required timeframe provisional registration may either be extended for a limited time or cancelled.

The Provisional approval pathway would also be available for extension of indications to certain medicines.

Provisional registration of a medicine differs from ‘full’ registration in several respects. Provisional registration is conditional on a sponsor obtaining a provisional determination; provisional registration will be subject to some different conditions than standard registration; and provisional registration will be time-limited. Further details of this scheme are set out below. Information about provisionally registered medicines will be communicated to

patients and health care professionals to inform their treatment decisions and maintain confidence in the TGA's regulatory standards.

### **Items 1 and 2**

Item 1 replaces the definition of 'registered goods' to mean therapeutic goods included in the part of the Register for goods known as registered goods and therapeutic goods included in the part of the Register for goods known as provisionally registered goods. Item 2 clarifies that a reference in the Act to therapeutic goods that are registered includes a reference to a medicine that is provisionally registered and a reference to the registration of therapeutic goods includes a reference to the provisional registration of the medicine.

### **Items 3 to 5**

Item 3 inserts new paragraph (aa) into subsection 6AAE(6) creating a new part of the Register for provisionally registered goods. Items 4 and 5 make consequential amendments to subsection 9A(3) providing for the Register to contain 5 parts, with the additional part being for provisionally registered goods.

### **Item 6**

Consequential on the inclusion of a medicine in the part of the Register known as provisionally registered goods, item 6 amends section 9D of the Act to provide for 2 new circumstances in which the Secretary may, on his or her own initiative, vary the entry in the Register.

Subsection 9D(1A) provides for the Secretary, on his or her own initiative, to vary an entry in the Register in relation to a provisionally registered medicine where it appears to the Secretary that the quality, safety or efficacy of the medicine is unacceptable in relation to a class of persons. The Secretary's power will be limited to variations that will reduce the class of persons for whom the medicine is suitable, to change the directions for use of the medicine, or to add a warning or precaution to the medicine. The warning or precaution must not compare the medicine with any other medicine by reference to quality, safety or efficacy.

Subsection 9D(1B) provides that the Secretary may also, after making a decision to extend the provisional registration period for a medicine under section 29(9), on his or her own initiative vary the entry in the Register to reduce the class of persons for whom the medicine is suitable, or to change the directions for its use.

Subsection 9D(1C) requires the Secretary, before making either of these variations, to inform the sponsor in relation to whom the medicine is registered in writing of his or her intention to make this variation and the reasons for it, and give them a reasonable opportunity to make a relevant submission. The Secretary must take those submissions into account before making a decision to vary the Register. Subsection 9D(1D) clarifies that it is not intended that making such a variation will create a separate and distinct good under section 16(1) of the Act.

### **Item 7**

Before sponsors of therapeutic goods can apply for provisional registration, they must obtain a provisional determination (i.e. a ‘designation’ or ‘entry ticket’ for the Provisional Approval pathway). Item 7 sets out the scheme for obtaining provisional determinations.

Under new subsection 22C(1), a person may apply to the Secretary for a provisional determination in relation to a kind of medicine prescribed by the regulations.

Subsection 22C(2) requires an application is made using the form approved in writing by the Secretary, is accompanied by the prescribed application fee, contains the information required by the form and any other information, statement or document required by the Secretary and meets any other requirement prescribed by the regulations. Subsection 22C(3) permits an approval of a form to be given in accordance with specified software requirements, on a specified kind of data processing device or by way of a specified kind of electronic transmission.

The Secretary is required, by subsection 22D(1), to consider an application made in accordance with subsection 22C(2) and either decide to make or refuse to make the provisional determination. Criteria of which the Secretary must be satisfied to make the determination will be set out in the regulations (subsection 22D(2)).

Subsection 22D(3) requires the determination to specify the person, the medicine, the indication and the active ingredient or ingredients of the medicine to which the determination relates, as well as any other matters the Secretary considers appropriate.

The Secretary is required by subsection 22D(4) to, as soon as practicable after making the decision, notify the person who applied for the determination in writing; if the Secretary refuses to make the determination, he or she must set out the reasons for refusal in the notice.

Subsection 22E(1) provides that a provisional determination relating to a medicine comes into force on the day on which the applicant is notified by the Secretary, and remains in force for an initial period – that is either 6 months, or another period prescribed by the regulations – unless the determination is revoked (see new section 22F below).

By subsections 22E(3) to (5), this initial period can be extended for a further period of six months if the applicant requests an extension at least 28 days before the determination expires and pays the prescribed application fee, and the Secretary agrees to extend the determination. The Secretary may grant an extension for by 6 months (or other period prescribed by the regulations) if satisfied that the criteria for initially obtaining the determination are still met, and that the applicant would, if the extension is granted, make an application for provisional registration under section 23 before the end of the extended period (subsection 22E(6)).

Applicants are limited to one request for an extension of a provisional determination (subsection 22E(8)), and must be notified by the Secretary in writing as soon as practicable after the decision has been made. If the Secretary refuses to extend the determination, he or she must set out the reasons for this decision in the written notice to the applicant.

If a person applies for provisional registration while the provisional determination is still in force (whether during the initial period of its operation or through an extension of the determination), the determination remains in force until it is withdrawn, it lapses by operation of subsection 24(2), the applicant notifies the Secretary that they wish the application to be treated as having been refused, or the application for provisional registration is finally determined (subsection 22E(9)). Subsection 22E(10) clarifies that the application is finally determined when the application, and any reviews or appeals arising from the application have been concluded.

Subsection 22F(1) enables the Secretary to revoke a provisional determination on his or her own initiative if she or he is satisfied that the medicine no longer meets the criteria for obtaining a determination. The Secretary must also, by subsection 22F(2), revoke the determination at the written request of the holder of the determination. The Secretary is required by subsection 22F(3) to notify the person specified in the determination of his or her decision in writing, setting out the reasons for the revocation, and subsection 22F(4) provides that the determination is revoked from the day on which the Secretary gives the person notice of the revocation.

### **Items 8 to 12**

These items set out the process for applying for provisional registration of a medicine.

Item 8 inserts section 23AA, which provides that if a person makes an application under section 23 for registration of a medicine, and a provisional determination is in force relating to the person, the medicine and the indication mentioned in the application, the application is taken to be an application for provisional registration of that medicine. This ties the application for registration to the specifications of the provisional determination as provided for by subsection 22D(3). The Department of Health (through the TGA) proposes to issue guidance on how it proposes that the specifications of the provisional determination will be relevant to the assessment of a provisional registration application.

Item 9 renumbers current paragraph 25(1)(d) to paragraph 25(1)(c) and inserts new paragraph 25(1)(d) that sets out the matters of which the Secretary must be satisfied when evaluating the medicine for provisional registration. The Secretary must carry out the evaluation having regard to whether, based on preliminary clinical data, the safety and efficacy of the medicine for the purpose for which it so be used have been satisfactorily established; whether the quality of the medicine for the purposes for which it is to be used has been satisfactorily established; and whether, if the Secretary were to register the medicine, the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine within six years of the commencement of provisional registration.

Item 10 inserts new section 28(2A), providing for the Secretary to specify conditions for the registration of a provisionally registered medicine.

### **Items 11 and 12**

These items amend section 29 of the Act to provide for a key feature of provisional registration – that it is time-limited. In broad terms, subsections 29(2) and 29(3) provide that, on the Secretary’s decision to provisionally register a medicine, it will remain on the Register for the provisional registration period of two years starting on the day registration commences, unless the registration is cancelled earlier. (Notes at the foot of subsections 29(2) and 29(3) provide (respectively) that a medicine is taken not to be included in the Register while its registration is suspended and that subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration).

Subsection 29(4) enables the person in relation to whom the medicine is provisionally registered to apply, no more than twice (see subsection 29(8)), to renew this registration on each occasion for a further period of up to two years (paragraph 29(7)(b)). The application must be made six months before the provisional registration period is due to expire, and must be in a form approved in writing by the Secretary, must contain the information the form requires, as well as any further information, statement or document the Secretary requires. The application must also be accompanied by the application fee prescribed by the regulations. (The note at the foot of subsection 29(8) clarifies that the Secretary may extend the provisional registration period on his or her own initiative.)

Subsection 29(6) requires the Secretary to make a decision to grant or refuse to grant an extension of the provisional registration period upon receipt of the extension application; in doing so the Secretary must consider whether the Secretary is satisfied with the applicant’s plan to submit comprehensive clinical data on the safety and efficacy of the medicine within six years of the first day of the medicine’s provisional registration. The Secretary may also take into account any other matters he or she considers relevant.

Subsection 29(7) obliges the Secretary, as soon as practicable after making the decision, to give the applicant notice of the decision in writing. If the Secretary decides to extend the provisional registration period, the notice must specify the duration of the extension (which must be two years or less); if the Secretary refuses to extend the provisional registration period, he or she must set out the reasons for this refusal in the notice. (The note at the foot of subsection 29(7) explains that at the time of granting an extension, the Secretary may impose new conditions on provisional registration or vary the existing conditions and refers to subsection 28(3).)

As referred to in the note at subsection 29(8), subsection 29(9) provides that if an applicant applies, during the term of the provisional registration, for registration of the medicine under section 23, the Secretary may in connection with the application under section 23 end or extend the provisional registration. In ending or extending the provisional registration period under subsection 29(9), the Secretary is required by paragraph 29(10)(a) to have regard to any matters prescribed by the regulations. The options that the Secretary might choose to exercise when making a decision under subsection 29(9) include, in circumstances where he or she has refused an application under section 23 for ‘full’ registration, allowing the provisional registration to continue until it expires; or extending the provisional registration for a further period, up to a maximum of six years after the provisional registration

commenced; or ending provisional registration at the same time as the decision not to register the medicine, due to safety concerns.

The Secretary is required to ensure that the provisional registration period continues while he or she is considering the application for 'full' registration is being considered unless registration is cancelled (paragraph 29(1)(b)). Provisional registration is limited to a maximum term of six years (under paragraph 29(10)(c)), unless it is extended during the Secretary's consideration of an application for full registration.

Provisionally registered goods may still be suspended or cancelled under the suspension and cancellation provisions in Part 3-2 of the Act.

### **Item 13**

Section 56A of the Act empowers the Secretary to certify certain matters under the Act in writing. Subsection 56A(3) provides that in proceedings for an offence under the Act, or a contravention of a civil penalty provision, a certificate made under subsection (1) of this section is prima facie evidence of the matters set out in the certificate. Item 13 of this Bill enables the Secretary to certify that, at a specified time or during a specified period, certain therapeutic goods were or were not included in the part of the Register for provisionally registered goods.

### **Items 14 to 17**

These items amend section 60 of the Act to limit appeals from decisions about provisional determinations and provisional registration. Item 14 makes a consequential amendment to subsection 60(2).

Item 15 inserts subsection 60(2AA) that provides that limits the persons who may apply to review of decisions by the Secretary (or a delegate) to vary an entry in the Register in relation to a medicine under subsections 9D(1A) or 9D(1B) to the person in relation to whom the medicine is registered.

Item 15 also inserts subsection 60(2AB) limiting the persons who may apply to review the following decisions by the Secretary to the person who applied to the Secretary to make the decision:

- The Secretary's decision to make, or refuse to make a provisional determination;
- The Secretary's decision to extend, or refuse to extend a provisional determination;
- The Secretary's decision as to whether an application for provisional registration passes preliminary assessment;
- The Secretary's decision to provisionally register, or not to provisionally register, a medicine;
- The Secretary's decision to revoke a provisional determination;

Reviews of decisions by the Secretary to extend, or refuse to extend provisional registration under subsection 29(6), or to end or extend the provisional registration period under subsection 29(9), following an application for standard registration of the medicine, may only be sought by the person in relation to whom the medicine is provisionally registered.

## **SCHEDULE 2 — Indications and ingredients for listed medicines**

### ***Therapeutic Goods Act 1989***

This Schedule principally contains amendments to introduce a new requirement for medicines that are listed in the Register under section 26A in relation to the indications that can be made for such medicines.

This Schedule contains amendments to enable the Minister to determine, by legislative instrument, a list of ‘permitted indications’ that can be made by medicine listed in the Register under section 26A. To be included in the list of permitted indications, indications will be assessed against a set of criteria to ensure that they are appropriate for low risk listed medicines that are not assessed prior to marketing in Australia. Amendments in this Schedule also enable the Minister to determine, by legislative instrument, a list of non-permitted indications that must not be used in medicines listed under section 26A.

Applicants for listing of medicines under section 26A will be required to use only those indications that are permitted for use in such medicines. This will have the effect of limiting the indications that can be made for listed medicines that are not subject to pre-market efficacy review. This will help prevent inadvertent non-compliance by sponsors and also provide greater protection for consumers on the safety, quality and efficacy of medicines available on the market.

This Schedule also contains amendments to approval and assessment process for new ingredients proposed for use in listed medicines.

### **Items 1 and 2**

Items 1 and 2 introduce amendments to section 26A to introduce new requirements in relation to the indications that applicants for listing can make to describe the therapeutic uses for their medicine.

When a person applies to list a medicine in the Register, they must certify that their medicine meets all relevant requirements for listing, such as: the medicine only contains permitted ingredients; the medicine complies with all safety and quality criteria, etc. Items 1 and 2 amend subsection 26A(2) to provide for additional certifications that an applicant must make when applying to list a medicine to require that the indications included in a listed medicine’s entry in the Register and on the medicine’s label must be included in a list of permitted indications. The list of permitted indications will be specified in a determination by the Minister under the new section 26BF (the permitted indications determination) (item 12 refers).

Item 1 inserts new subparagraphs 26A(2)(fba)(i) and 26A(2)(fba)(ii) which require the applicant to certify that:



- any indication included on the medicine’s label is covered by the permitted indications determination
- each permitted indication included on the medicine’s label is also included in the medicine’s entry in the Register.

Item 2 inserts new paragraphs 26A(2)(fd) and 26A(2)(fe) which will require the applicant to certify that:

- any indication included in the Register is covered by the list of permitted indications
- the medicine complies with any requirements relating to the use of a permitted indication in a listed medicine.

The effect of items 1 and 2, taken together, is that the Register entry for medicines listed under section 26A and their labels must only contain certain low level permitted indications, and that there must not be inconsistency between the indications that are listed in the Register and on the label (as would be seen by the purchaser or user of the listed medicine).

However, it is intended that there will be some flexibility around how applicants can use selected permitted indications for their medicine. Permitted indications included in a medicine’s entry on the Register will not be required to be included ‘word for word’ on that medicine’s label, rather the indication in the Register and on the medicine label must be ‘covered by’ the new list of permitted indications. An indication will be taken to be ‘covered by’ the new permitted indications determination, if the indication:

- is specified in the determination
- is a more specific version of an indication specified in the determination, for example because the indication is specified for use in a certain target population or for a particular time of use
- when used on the medicine label, the indication does not differ in intent or meaning from the indication as specified in the determination and included in the medicine’s Register entry. For example: if the indication: ‘Maintain/support gastrointestinal health’ was included in a medicine’s entry in the Register:

§ ‘Maintains a healthy gut’ would be considered to have the same meaning; but

§ ‘Maintains healthy intestinal flora’ would be considered to have a different meaning.

Consistent with current arrangements for medicines listed under section 26A, an incorrect certification by a sponsor in relation to these matters, for example because a medicine makes an indication that is not covered by the determination, will be a basis upon which to cancel the listing of medicine from the Register (items 15 and 16 refer).

### **Items 3, 4 and 5**

The current applicant certification requirements under subsection 26A(2) do not distinguish between claims that are therapeutic indications and claims that are not therapeutic indications, such as product marketing claims e.g. ‘Now more effective’. The different types of claims for listed medicines have, historically, not been distinguished because a sponsor is required to hold evidence to support all claims (i.e. both ‘therapeutic’ and ‘marketing’) made for their medicine. However, while an applicant is required to hold evidence to support any claim, only therapeutic indications are required to be included in the listed medicine’s entry in the Register.

Items 3 and 4 provide clarity for applicants by confirming that applicants are required to hold evidence to support all non-indication (e.g. marketing) claims and therapeutic indications made for their medicine. Item 3 amends paragraph 26A(2)(j) to require that sponsors hold evidence to substantiate non-indication claims proposed to be made for their medicine. Item 4 introduces new subparagraphs 26A(ja)(i) and 26A(ja)(ii) requiring that the applicant certifies that they hold evidence to support each permitted indication proposed to be included in the Register for their medicine.

Item 5 introduces a new section 26A(2B) that empowers the Minister to specify, by legislative instrument, evidence requirements for medicines listed under section 26A. Such an instrument may prescribe the amount, standard and type of evidence required to support indications and non-indication therapeutic claims. Applicants will therefore be required to certify that the evidence they hold for their medicine meets the requirements contained in the instrument, where made.

The requirement for an applicant of a listed medicine to hold evidence to support each indication made for the medicine is not new. Currently sponsors must comply with the document ‘Evidence guidelines: Guidelines on the evidence required to support indications for listed complementary medicines’ as amended from time to time. Specifying evidence requirements in a legislative instrument will make the evidence requirements that apply to a medicine from the time of listing clear on the face of the law and provide clear grounds for regulatory decision making.

### **Items 6 and 7**

Currently, for a new ingredient to be included in the Therapeutic Goods (Permissible Ingredients) Determination, an applicant is required to submit a data package to the Secretary that demonstrates the safety and quality of the ingredient. If the Minister is satisfied with the safety and quality of the ingredient, the ingredient will be approved for use in listed medicines and included in the Therapeutic Goods (Permissible Ingredients) Determination. Any sponsor can then include that ingredient in a medicine and list that medicine in the

Register without having to undertake the necessary research to support the safety and quality of the ingredient.

Item 6 introduces a new subsection 26BB(2A) which will empower the Minister to permit a successful applicant for a new permitted ingredient to have exclusive use of that ingredient (the protected ingredient) for a specified period of time. The exclusivity period will be specified in the Therapeutic Goods (Permissible Ingredients) Determination as a 'requirement' relating to the use of the ingredient in listed medicines under paragraph 26BB(1)(b).

The intended effect of the requirement will be to restrict the use of a protected ingredient in a listed medicine within the exclusivity period to the ingredient applicant (who may or may not be a medicine sponsor) or by other persons nominated by the applicant. The ingredient could not be used by other applicants to list a medicine in the Register unless they have been nominated by the ingredient applicant during the exclusivity period. Use of a protected ingredient within the exclusivity period without an approval from the ingredient applicant would contravene the requirement relating to the use of the ingredient and, consistent with current arrangements, provide grounds to cancel the medicine from the Register under paragraph 30(1)(e).

At the end of the exclusivity period, the exclusive approval would revert to a general approval and any sponsor can use the ingredient to list a medicine in the Register. The intent of specifying an exclusivity period for use of new ingredients is to recognise the resources invested by innovators who research and develop new ingredients to be used in listed complementary medicines. It is the policy intention that the exclusivity period would only be available in respect of new ingredients that have not previously been evaluated by the TGA for use in registered or listed goods.

Item 7 amends subsection 26BB(4) to make clear that the Minister's power to specify requirements relating to the use of ingredients in a medicine under paragraph 26BB(1)(b), is not limited to specifying an exclusivity period for new ingredients under the new subsection 26BB(2A). That is, the Minister will be able to impose any other requirements relating to the use of an ingredient that he or she considers necessary for the safe and effective use of the ingredient in a listed medicine.

### **Item 8**

Item 8 inserts the heading 'Making an application for recommendation' before subsection 26BE(1) which relates to requirements for applications to the Secretary for a recommendation to vary the Therapeutic Goods (Permissible Ingredients) Determination as made under section 26BB.

### **Items 9, 10, 11 and 12**

These items introduce a range of amendments to support the introduction of legislated timeframes for assessments of applications for new ingredients proposed for use in listed medicines.

Item 9 introduces new paragraphs 26BE(2A) and 26BE(2B), which require an applicant (for a proposed new ingredient for use in listed medicines) to provide any additional information requested in writing by the Secretary, within the time frame specified, in order for the application to proceed. This is based on the existing arrangements under subsection 26BE(8) which is being repealed (see item 12). However, under new paragraph 26BE(2B), an application for a new ingredient will be considered to have lapsed and, therefore, no longer able to be considered, if the required information is not provided within the specified time frame.

Item 10 introduces a new paragraph 26BE(3)(c), which provides that if the applicant gives the information as requested by Secretary, within the specified time frame, then the Secretary must proceed with the evaluation of the ingredient.

These amendments are intended to ensure that applicants provide complete information for assessment and to allow the Secretary to assess this information in a timely manner.

Item 11 introduces new subsection 26BE(5A), to make clear that, if the Secretary decides to not recommend the approval of an ingredient for use in listed medicines, the Secretary must notify the applicant of the refusal and provide reasons for the decision. A decision under this section (to refuse to make a recommendation to the Minister to approve a new ingredient for use in listed medicines) is a reviewable decision under section 60 of the Act.

Item 11 also inserts subsection 26BE(5B) which provides that, where the regulations specify a timeframe within which assessments must be completed and, the Secretary does not make a decision within this time, 25% of the applicable evaluation fee must be refunded to the applicant.

Item 11 also inserts subsection 26BE(5C) which provides that, where the regulations specify a timeframe within which assessments must be completed and, the Secretary does not make a recommendation within this time, the applicant may give written notice to the Secretary that they wish to treat their application as having been refused. Such a notice may be given to the Secretary at any time before the evaluation is completed (subsection 26BE(5D)).

New subparagraphs 26BE(5E)(a) to (c) have the effect that, if an applicant gives written notice to the Secretary that they wish to treat their application for a new ingredient as having been refused, the applicant can bypass the internal review process of the Secretary's decision and appeal the deemed refusal directly to the Administrative Appeals Tribunal.

The amendments made by item 11 are being introduced to support the introduction of legislative timeframes for ingredient applications and to provide greater certainty and predictability for ingredient applicants.

Item 12 repeals subsection 26BE(8) which allows the Secretary to request additional information from an applicant for a new ingredient. These provisions are now included in new paragraphs 26BE(2A) and 26BE(2B), added under item 9.

Item 13 removes reference to the repealed subsection 26BE(8) (item 11 refers) and includes reference to the new paragraph 26BE(2A) (item 8 refers) allowing the Secretary to require any additional information (that may be requested from an applicant for a new ingredient) to be provided by way of a specified data processing device or electronic transmission.

#### **Item 14**

The new subsection 26BF provides for the establishment of a list of indications (therapeutic uses) permitted to be made by medicines that are listed in the Register under sections 26A and requirements relating to their use in such medicines. The intention of establishing a list of permitted indications is to ensure that complementary medicines that are not subject to pre-market efficacy review by the Secretary are appropriately limited in the indications that can be made.

#### *Permissible indications*

Subsection 26BF(1) empowers the Minister to specify indications that are permitted for listed medicines (i.e. the permitted indications list) in a legislative instrument (the permitted indications determination). The permitted indications list and associated requirements for their use in listed medicines are specified by legislative instrument, rather than primary legislation, so as to provide a timely mechanism to add new indications either on the Minister's initiative under the new section 26BH or following an application made under the new section 26BJ. This will ensure the 'fast to market' approval process for sponsors to list medicines in the Register under section 26A is retained. This will also allow timely amendments to requirements included in the list in circumstances where a potential safety concern with a particular ingredient arises.

The new subsection 26BF(2) deals with the matters that the Minister may consider when deciding whether an indication is appropriate for inclusion in the permitted indications determination. The criteria are intended to ensure that indications that may be used in listed medicines are low risk and are appropriate for medicines that are not assessed pre-market.

These include that indications may only refer to:

- Health maintenance, which includes normal physiological growth, development and normal functions of the body. For example: 'supports healthy liver function'.
- Health enhancement, including by targeting natural biological factors, the physiological and/or psychological state of the body above and beyond normal growth, development and functions of the body, for example: 'stimulates digestive function'.

- Prevention or alleviation of a non-serious vitamin or mineral dietary deficiency or skin cancer, for example: 'helps prevent dietary vitamin D deficiency'.
- Non-serious forms of a disease, condition, ailment or defect. These include self-diagnosable and/or self-manageable conditions, where a delay in medical treatment would not be detrimental to the consumer. Indications may also relate to reduction in risk, frequency, severity, duration or relief of symptoms without resolution of the underlying non-serious disease, ailment, defect or injury. For example: 'helps reduce occurrence of eczema/dermatitis'.

The new subsection 26BF(3) provides that, the Minister is not limited to the criteria listed above and could also have regard to any other matter he or she considers relevant. This could include for example, whether the indication:

- uses terminology that is appropriate for the evidence that supports its use (scientific evidence or a history of traditional use). For example, indications based on a 'tradition of use' must not use terminology that would require a scientific procedure or investigation to verify, such as: 'increase bone density'
- would be capable of complying with the Therapeutic Goods Advertising Code when included on the product label or promotional materials. For example, to comply with the Advertising Code, a permitted indication linked to ingredients or product formulation must not mislead, or be likely to mislead consumers. To be considered not misleading, the indication must be able to be supported by currently available scientific knowledge or a documented tradition of use.

Using these criteria, the permitted indications determination will specify indications that can be made for medicines listed under section 26A (i.e. a list of indications) as well as criteria for how specified indications can be modified by listed medicine applicants. The criteria will therefore provide the circumstances in which such a modified indication will remain covered by the determination (i.e. for the purposes of the new applicant certification provisions that the Register entry and the labels for a listed medicine only contain permitted indications (items 1 and 2 above refer)).

For example, an applicant could modify an indication by specifying:

- a target population, such as in 'in the elderly'
- a time of use, such as 'after exercise'
- context of traditional use, such 'traditionally used in Chinese medicine'.

The policy intention is that, any modification of a permitted indication must not change the intent or meaning of the indication, rather, these arrangements will allow sponsors to tailor a specified indication to align with the evidence that they hold for their medicine.

#### *Requirements for permitted indications*

The new paragraph 26BF(1)(b) and new subsections 26BF(4) and 26BF(5) provide the Minister with the ability to specify requirements relating to the use of permitted indications when used in listed medicines. This provides the Minister with a mechanism to ensure that indications included in the determination are appropriate for low risk listed medicines that are not assessed pre-market. The requirements specified by the Minister may:

- specify circumstances when an indication can or cannot be used, for example: certain indications have a requirement that they must not be indicated for use in children
- specify conditions that must be met for an indication to be used, such as label advisory statements, for example: ‘if symptoms persist consult your healthcare practitioner’
- specify the type of evidence required to support the use of certain indications, for example: scientific or a tradition of use.

#### *List of non-permitted indications*

The new section 26BG provides for the establishment of a list of indications that must not be used in a medicine listed in the Register under section 26A.

Subsection 26BG(1) empowers the Minister to specify indications (therapeutic uses) that are not permitted for use in listed medicines in a legislative instrument. These are indications that might otherwise meet criteria for inclusion in the list of permitted indications but for which it is inappropriate that they be used in medicines that are not pre-market assessed. The new subsection 26BG(2) provides that the Minister may include an indication in the list of non-permitted indications either generally or in certain specified circumstances.

In relation to the circumstances in which the proposed new power might be used to exclude indications for use in listed medicines, it is intended that this would only occur where there are very clear reasons for doing so. An indication may require inclusion on the non-permitted list where, in the interest of consumer safety or for consistency with the Government’s public health messages, it is appropriate the medicine is assessed through a pre-market assessment pathway which could include the registration pathway or the new pathway for assessed listed medicines (Schedule 3 refers). For example, indications and claims relating to smoking cessation or obesity.

The ‘non-permitted indications list’, if made, will be specified by legislative instrument, rather than primary legislation to enable timely amendments to the instrument when required in response to emerging public health issues. By reason of operation of subsection 33(3) of the *Acts Interpretation Act 1901*, the new section 26BH enables the Minister to add, remove or amend indications included in the list of non-permitted indications at his/her own discretion.

#### *Applications for recommendation to vary the permitted indications determination*

The new section 26BJ provides for applications to be made for new indications to be added to the list of permitted indications. Under the proposed arrangements, a person may apply to the Secretary for a recommendation that the Minister vary the permitted indications determination (the new section 26BF refers).

The new subsections 26BJ(1) and (2) provide that an applicant can apply to the Secretary for a new indication to be considered and that the application must be: in writing; in the approved form; delivered to the relevant specified Departmental office; and accompanied by the applicable fee which will be prescribed by the regulations.

#### *Limits on the kinds of applications that can be made*

Subsections 26BJ(3),(4) and (5) sets limits on the kinds of applications that can be made and provides that an applicant cannot apply for an indication that:

- is specified in a non-permitted indication determination (the new section 26BG refers)
- refers to a restricted representation (section 42DD refers)
- refers to a prohibited representation (subsection 42DJ(1) refers), other than representations relating to skin cancer where the representation has been permitted by the Secretary under section 42DK
- refers to preventing, curing or alleviating a disease, ailment, defect or injury, other than prevention of a dietary deficiency or prevention of skin cancer or sun damage for listed therapeutic sunscreen products.

Indications that relate to the above matters are not low risk and are unsuitable for medicines that are not assessed pre-market.

#### *Further information about application for recommendation and lapsing of applications*

The new subsection 26BJ(6) provides that the Secretary may request additional information from the applicant in relation to the proposed indication and that this must be provided within the timeframe specified in the request. Additional information about a proposed indication may be necessary where, for example, it is unclear whether a proposed indication meets the eligibility criteria for permitted indications or where there are concerns that a proposed indication does not meet other requirements for listing, such as those relating to advertising. Subsection 26BJ(7) provides that the application will be considered to be lapsed and, therefore, no longer able to be considered, if the required information is not provided within the requested timeframe.

#### *Decision on application for recommendation*

Subsections 26BJ(8) to (10) set out the steps that the Secretary must take when considering an application to add a new indication to the list of permitted indications.

Subsection 26BJ(8) states that if the applicant has provided the application in the appropriate form, provided any additional information requested within the specified timeframe and paid



the applicable fees, then the Secretary must make a decision to recommend or refuse to recommend the proposed indication to the Minister. In deciding whether to refuse or recommend the proposed indication, the Secretary may consider the criteria listed in the new subsection 26BJ(9). These criteria are largely similar to those in the proposed subsection 26BF(2) relating to health maintenance and health enhancement etc. above and are intended to be applied in the same way.

Subsection 26BJ(10) provides that if the Secretary does not recommend the indication for approval, the applicant must be informed in writing and provided with reasons for the decision. The effect of this step, i.e. for persons to apply at first instance to the Secretary, and for the Secretary to either make a recommendation to the Minister about a variation or to refuse to do so, is to provide for review and appeal rights for such applicants (item 20 below refers).

#### *Minister may vary a determination*

Subsections 26BJ(11) to (13) set out the steps that the Minister must take when considering an application to add a new indication to the list of permitted indications.

The new subsection 26BJ(11) provides that, if the Secretary recommends that the Minister vary the permitted indications determination to include a new indication, the Minister must decide to either vary or refuse to vary the list of permitted indications to include the indication.

Subsection 26BJ(12) provides that, in making this decision, the Minister may consider the Secretary's recommendation and whether the indication meets the criteria for a permitted indication as provided in the new subsection 26BJ(9).

Subsection 26BJ(13) provides that the Minister is not limited to the criteria listed above and could also have regard to any other matter he or she considers relevant.

#### *Applications or information may be given electronically*

Subsection 26BJ(14) provides that the approved form for applications for proposed new permitted indications, or requests by the Secretary for additional information in relation to such applications, may be required to be submitted electronically.

### **Items 15 and 16**

These items make amendments to the automatic conditions that apply to medicines when they are listed in the Register under section 26A.

Currently subsection 28(6) provides a condition of listing that a sponsor must hold evidence to support any claim made in relation to the medicine. However, this does not distinguish between non therapeutic claims and therapeutic indications. To address this issue, items 15

and 16 repeal the current subsections 28(6) and 28(7) and replaces them with new subsections 28(6) and 28(7).

New subsection 28(6) provides that the listing of medicines in the Register under section 26A is subject to the condition that the sponsor must have: evidence for any claim (other than an indication) made in relation to the medicine; continue to hold that evidence while the medicine remains listed in the Register; and provide that information to the Secretary, if requested to do so.

New subsection 28(7) provides that the listing of medicines in the Register is subject to the condition that the applicant must have: evidence for any indications included in the medicine's entry in the Register; continue to hold that evidence while the medicine remains listed in the Register; and provide that information to the Secretary, if requested to do so.

For paragraphs 28(6)(a) and 28(7)(c), the amount, standard and type of evidence required to support indications and non-indication therapeutic claims may be prescribed in an instrument made under the new subsection 26A(2B) (item 5 refers).

The effect of these amendments is to clarify existing arrangements and to make the sponsor's obligation clear with respect to the holding of information to substantiate all non-indication claims and therapeutic indications made for their medicine.

### **Items 17 and 18**

Items 17 and 18 introduce amendments to provide for circumstances when the Secretary may cancel a listing in the Register where the new requirements in relation to permitted indications are not complied with. Item 17 amends paragraph 30(1)(e) to provide for the circumstances when the Secretary will be able to immediately cancel a medicine listed in the Register if the certifications made by the sponsor at the time of listing under new paragraphs 26A(2)(fba), (fd) and (fe) are incorrect (item 1 and 2 refer). This will be the case where:

- the medicines label and Register entry contain an indication that is not covered by the permitted indications determination
- the requirements relating to the use of an indication have not been complied with (item 14 refers).

These provisions are consistent with arrangements that apply when the requirements in relation to permitted ingredients are not complied with.

Consistent with current arrangements, item 18 amends paragraph 30(2)(ba) to provide that the Secretary may cancel a medicine listed in the Register where the sponsor does not hold sufficient evidence to support indications and claims that are made for the medicine.

Currently this paragraph does not distinguish between non-indication claims and therapeutic indications. Note that subsection 30(3) requires the Secretary, before cancelling the entry, to inform the person in writing that the Secretary intends to cancel the entry and provide the person with a reasonable opportunity to respond to the notice.

### **Item 19**

Decisions by the Secretary (or a delegate) in relation to applications for a recommendation to vary the permitted indications determination (the new section 26BJ refers) will be subject to the review provisions of section 60, as they are considered “initial decisions” for the purpose of that section (due to paragraph 60(1)(c)). Subsection 60(2) of the Act currently sets out that a person whose interests are affected by an initial decision may, by written notice, request the Minister to review that decision.

Item 19 introduces a new subsection 60(2C) to provide that, only the person who applied for a new permitted indication can request a review of a decision to refuse the application. That is, a person other than the applicant of the application cannot request a review of the decision for that application.

The scope of the existing section 60 appeal mechanism provided by subsection 60(2) is not appropriate for new indications, as the range of ‘interested parties’ could potentially extend to a large number of people (other than the applicant) and create significant uncertainty in the predictability in the application process (under the new 26BJ). There is a public interest in having certainty and finality about rights of review for those about whom a regulatory decision is made.

It should be noted that existing review rights for applicants and third parties relating to the listing of medicines in the Register under section 26A of the Act are not affected by this change.

#### **Item 20**

New paragraph 63(2)(daaa) provides for regulations to be made to specify timeframes for applications for new ingredients that are assessed under section 26BE for use in listed medicines.

#### **Item 22**

##### *Application of amendments*

Subitems 22(1) to (5) provide the arrangements for how the amendments made by the Schedule are to be applied.

Subitem 22(1) provides that the amendments to 26A apply to listed medicine applications made after commencement of this Schedule. This means that:

- any applications to list a medicine in the Register under section 26A after this day will have to comply with the new provisions set out in the Schedule
- certifications made by the sponsor of medicine listed under 26A before the commencement of this Schedule will continue to apply to that medicine while it remains in the Register (i.e. until the end of the transition period).

Subitem 22(2) provides that the amendments to 26BE apply for new permitted ingredient applications after commencement of this Schedule.

The effect of subitem 22(3) is that the initial permitted indications determination may include indications that do not meet the criteria for permitted indications specified in subsection 26BF(2).

Subitem 22(4) provides that the amendments to section 28, in relation to the sponsor's obligation to hold evidence to support therapeutic indications and claims, apply to medicines listed in the Register under section 26A after commencement this Schedule.

The effect of subitem 22(5) is that the amendments to section 30, in relation to circumstances when the Secretary may cancel a listing in the Register where the new requirements in relation to permitted indications are not complied with, apply to medicines listed in the Register under section 26A after commencement of this Schedule.

### **Item 23**

#### *Scope of transitional provisions*

Item 23 provides for transitional arrangements for medicines that are currently listed in the Register under section 26A. The transition period is 3 years after the commencement of this Schedule.

To maintain continuous legal supply of a medicine listed under section 26A before the commencement of the Schedule, the sponsor must reapply to list their product in the Register under section 26A or the new section 26AE before the end of the transition period. In relation to applications to list a medicine under section 26A, this will involve: selecting appropriate indications from the permitted indications determination; and re-certifying the matters under section 26A that their medicine is compliant with the regulatory requirements. In relation to applications to list a medicine under section 26AE, this will involve making an application under the new section 26AB and providing data to the Secretary for assessment.

Subitems 23(1), (2) and (3) describe what medicines are covered by the transition period (transitioning medicines). This includes:

- medicines listed in the Register, under section 26A, immediately before commencement of this Schedule
- medicines for which an effective application to list the medicine was made, under section 26A, immediately before the commencement of this schedule; and the medicine is listed in the Register after commencement of the Schedule
- medicines that were listed in the Register, under section 26, before 11 June 1996 and that are not export only medicines.

#### *Reapplying for listed of certain medicines to include permissible indications*

Subitem 23(4) provides that a sponsor of a transitioning medicine may apply to re-list their medicine in the Register under section 26A or the new section 26AE of the Act (Schedule 3 refers).

*Cancellation of listing if further application not made and listing not otherwise cancelled during transition period*

Subitems 23(5) and (6) have the effect that a transitioning medicine will be cancelled from the Register at the end of the transition period, unless one of the following occurs before the end of the transition period:

- the medicine is re-listed under section 26A (i.e. the Register entry only includes permitted indications)
- the medicine undergoes pre-market assessment by the Secretary and is listed under the new section 26AE (Schedule 3 refers)
- the sponsor of the medicine applies to list the medicine under the new section 26AE in accordance with section 23B, but there has been no decision on the application at the end of the transition period.

These arrangements will ensure a smooth transition for medicines currently listed under section 26A to being listed under the new section 26AE.

Subitem 23(7) provides that, if an application is made to list a transitioning medicine under the new section 26AE, but that application lapses after the transition period, then that medicine's listing under section 26A is taken to be cancelled on the day the application lapses.

Paragraphs 26A(1)(e) and the new 26AB(1)(g) (Schedule 3 item 4 refers) provide that, where a medicine has previously been cancelled from the Register, the Secretary does not have to list the medicine under sections 26A or 26AE, respectively. However, Subitems (8) and (9) provide that, if the cancellation of the medicine was only due to the medicine not transitioning by the end of the transition period (subitem 6) or due to a lapsed application after the end of the transition period (subitem 7), then the Secretary must list the medicine if all other requirements are met.

*Cancellation of listing under section 26A if application under section 26AE made but not decided during transition period*

Subitems 23(10) and (11) provide that, where an application to list a medicine under section 26AE is made in accordance with section 23 and passes preliminary assessment, but no decision has been made on the application before the end of the transition period, then the medicine's listing under section 26A will be cancelled at the same time that the Secretary makes a decision to list, or to refuse to list the medicine under the new section 26AE(3).

This is to prevent the situation where an applicant submits an application to list a medicine under the new section 26AE late in the transition period giving the Secretary insufficient time make a decision about the application.

### **SCHEDULE 3 – New pathway for listed medicines**

This Schedule contains amendments to introduce a new assessment pathway in Part 3-2 of the Act to list medicines in the Register under a new section 26AE.

It is intended that the new pathway for ‘assessed listed medicines’ will allow medicines to be included in the Register following sponsor self-assessment and certification of the safety and quality of the product, coupled with assessment of the efficacy evidence supporting the proposed claims and indications by the Secretary. This new pathway will allow sponsors to apply to list medicines in the Register that make higher-level indications than are allowable under the current listing pathway, i.e. fall outside the permitted indications list (Schedule 2 refers) but which are still appropriate for lower risk listed medicines.

Criteria for these medicines have been developed following consultation with sponsors, consumers and health care professionals. For complementary medicines that have been assessed for efficacy as part of the market authorisation process, sponsors will be able to use promotional material to indicate that a product has been assessed as efficacious.

Implementation of this change will improve the evidence base of the sector and encourage innovation.

In all other respects these medicines must meet the current eligibility criteria for listed medicines (e.g. contain only permitted ingredients and be manufactured according to the principles of Good Manufacturing Practice).

#### **Item 1 and 2**

Item 1 amends paragraphs 21A(1)(b), 2(b) and 4(b) to provide that it is a general criminal offence to make a false statement in or connection with a certification for a medicine entered in the Register under the new pathway for assessed listed medicines. The matters that an applicant will be required to certify to list a medicine in the Register are outlined in the new section 26AB (item 3 refers).

Item 2 amends subsection 21B(1) to provide for civil penalties in relation to a breach of a condition of listing for medicines listed in the Register under the new section 26AE (item 3 refers).

#### **Item 3**

Item 3 amends paragraph 26(1)(ba) to make clear that medicines that are eligible to be listed under the new section 26AE must not be listed under section 26.

These offences and civil penalty provisions are the same as those that apply currently to medicines listed in the Register under section 26A.

## Item 4

### *Application for listing of certain medicines following efficacy evaluation*

The new section 26AB provides for applications to be made to list medicines in the Register under the new section 26AE. Subsection 26AB(1) provides that the Secretary must accept an application for evaluation if the requirements of that subsection are met. These include that:

- the application is made under section 23 and passes preliminary assessment (paragraphs 26AB(1)(a) and 26AB(1)(b))
- the medicine is not one that can be listed under section 26 or 26A, or that meets the criteria for listing under one of those sections (i.e. because the medicine indications are permitted indications or meet the criteria for inclusion in the permitted indications determination made under section 26BF) (paragraphs 26AB(1)(d) and 26AB(1)(e))
- the medicine is not one that has previously had its registration or listing cancelled (paragraph 26AB(1)(f)).

In order for a medicine to be listed on the Register through this new pathway it must comply with all legislative requirements in relation to quality, safety and efficacy. Subsection 26AB(2) sets out the matters that an applicant must certify when applying to list a medicine under the new section 26AE. These matters are largely similar to the matters applicants are currently required to certify to list a medicine in the Register under section 26A and include, among other things, that the medicine:

- is safe for the purposes for which it is intended to be used (paragraph 26AB(2)(b))
- is manufactured under Good Manufacturing Practice (GMP) (paragraph 26AB(2)(h) and subsection 26AB(4))
- complies with all applicable standards (paragraph 26AB(2)(f))
- is eligible for listing under the new section 26AB as prescribed in the regulations (paragraph 26AB(2)(a)).

The applicant certification provisions reflect the policy intention that sponsors of medicines listed in the Register under section 26AE will self-assess the quality and safety of the product against established criteria as described below.

In relation to whether a medicine is eligible for listing in the Register under section 26AE, criteria will be set out in the regulations. These will be similar to the eligibility criteria for medicines listed under section 26A and will include that:

- the medicine contains only permitted ingredients and meets the requirements associated with their use in listed medicines
- ingredients in the medicine are not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard
- the medicine must not be required to be sterile.

These criteria will support the requirement that medicines listed in the Register under the new section 26AE are of low risk. In contrast to the lowest risk medicines listed under 26A, however, medicines eligible for listing in the Register under section 26AE are not limited to only utilising permitted indications. Rather the intention is that they can make certain higher-level indications that exceed the criteria for low level permitted indications (the new subsection 26BJ(2) refers). It is intended for example, that products assessed through the new pathway may make indications:

- that refer to a serious disease (i.e. restricted representations) within the meaning of Part 5-1 but not the prevention or alleviation etc. of such a disease
- that refer to the prevention or alleviation of a non-serious form of a disease, ailment, defect or injury.

Allowing such medicines to be supplied without being individually assessed for efficacy would constitute unacceptable risk for these products.

To reflect their low risk nature, it is not intended that products assessed through the new pathway are able to make indications that:

- refer to the prevention, diagnosis, cure or alleviation of a serious form of disease, disorder or condition (i.e. restricted representations) within the meaning of Part 5-1); or
- contain a prohibited representation within the meaning of Part 5-1.

Consistent with current arrangements, medicines making these types of indications will continue to require approval through the registration pathway under section 25.

Under the proposed new subsection 26AB(4) a sponsor seeking to list a medicine under the new section 26AE must supply evidence that each overseas manufacturer involved in the manufacture of the product has acceptable manufacturing and quality control procedures in place. It is also a condition of ongoing listing that such evidence is supplied to the Secretary on request. In deciding whether to certify the manufacturer, the Secretary may have regard to the matters set out in the new subsection 26AB(5). The relevant fees and charges for these assessments will be prescribed in the regulations. This is consistent with the existing arrangements that currently apply to registered and listed goods under sections 25(1)(g) and 26A(3).

Consistent with the current arrangements for medicines listed under section 26A, subsection 26AB(6) requires applicants for the listing of medicines under the new section 26AB to seek pre-clearance of animal derived ingredients from the Secretary before making an application. This is to ensure that medicines containing such ingredients do not present an unacceptable safety risk to consumers.

Subsections 26AB(7), 26AB(8) and 26AB(9) provide that paragraph 26AB(2)(h) and subsection 26AB(4), which provide for requirements in relation to manufacture of medicines



under GMP, do not apply if the manufacturer is exempt from these requirements by operation of Part 3-3 of the Act.

*Evaluation fees for listing of medicine under section 26AE*

The new section 26AC provides for the payment of an evaluation fee for applications evaluated under section 26AE. The Secretary must notify in writing an applicant who submits an application that has passed preliminary assessment under section 26AB of the amount of the evaluation fee, which will be specified in, or determined in accordance with the regulations.

Subsection (4) provides that, where an application is accepted for evaluation, the evaluation fee becomes due and payable on the day the applicant is notified of the amount. Evaluation fees may be recovered as a debt due to the Commonwealth.

Subsection (5) provides for the refund of 25% of the applicable evaluation fee if the evaluation of the application is not completed within the maximum evaluation period, if set, by the regulations. This is in keeping with the proportion of the fee refunded for a registered prescription medicine application, if such an application is not completed within the maximum evaluation period, if set, by the regulations.

Subsection (6) requires that the Secretary notify the applicant in writing of the day the evaluation is completed. This is necessary to determine if the evaluation is completed within the period, if set, under the regulations.

*Lapsing and deemed refusal of applications for listing of medicine under section 26AE*

The new section 26AD provides the circumstances where an application made under section 26AB is taken to have lapsed and, therefore, the application is no longer able to be considered for listing of the medicine in the Register under section 26AE. Another application may be made to list the medicine and the requirements set out at section 26AB apply to that new application.

The lapsing provisions allow the Secretary to cease evaluation:

- if any part of the applicable evaluation fee remains unpaid at the end of the period of 28 days after the day on which the part become due and payable; or
- if the application or other information provided in connection with the application includes information that is inaccurate or misleading in a material particular.

This section also gives applicants the option of treating their application as having been refused where the Secretary fails to assess the application within the time limit, if any, set by the regulations. Applicants may give a notice to the Secretary at any time before the evaluation is completed that they wish to treat the application as having been refused. This

will be treated as a decision by the Minister confirming the decision of the Secretary to refuse to list the product in the Register. This has the effect of allowing the applicant to bypass the internal review process and appeal directly to the Administrative Appeals Tribunal.

### **Section 26AE Evaluation and listing of certain medicines**

This section provides for the evaluation of applications and the information submitted with applications and the steps the Secretary must take after completing the evaluation process.

#### *Evaluation*

The new subsection 26AE(1) obliges the Secretary to evaluate a medicine for which an application for listing has made and which has passed preliminary assessment. The Secretary must evaluate the medicine having regard to whether the efficacy of the medicine has been satisfactorily established.

This is a broad discretion allowing the Secretary to have regard to any matter he or she considers relevant. This could include for example, confirming that the presentation of the medicine is not unacceptable and other matters relating to the safe and effective use of the medicine. 'Presentation' in relation to therapeutic goods means, the way in which the medicine is presented for supply and includes:

- the medicine name and directions for use
- labelling and packaging, including any necessary warning and cautionary statements
- the medicine dosage form
- whether or not the medicine complies with advertising requirements, including Part 5-1 of the Act, the regulations and applicable provisions of the Therapeutic Goods Advertising code.

#### *Secretary must decide whether to list the medicine*

Subsection 26AE(3) makes it clear that after the Secretary has completed the evaluation, he or she must make a decision to list the medicine, or not to list the medicine.

#### *Decision to list*

The new subsection 26AE(4) to (7) sets out the steps that the Secretary must take to list the medicine in the Register when an application has been successful.

If the decision is to list the medicine, the Secretary must notify the applicant in writing that the goods will be included in the Register within 28 days of making the decision if the applicant gives the Secretary the certificate in relation to patents required under subsection 26B(1) or a notice that such a certificate under that subsection is not required. Where the applicant has provided to the Secretary the certificate or notice required under subsection

26B(1), the Secretary must include the goods in the Register without inquiring into the correctness of the certificate or notice.

Once the medicine is listed in the Register, the sponsor can, subject to any applicable conditions, import, export and supply the medicine in Australia from the day specified.

#### *Decision to refuse to list*

If the decision is to refuse to list the medicine, subsection 26AE(9) requires the Secretary to notify an applicant of the decision and provide reasons for the decision within 28 days of making the decision. A decision to refuse to list a medicine under this section is a reviewable decision under section 60 of the Act.

#### **Item 5**

This item amends the current section 26BA to provide that an approved form for the certificate or notice in relation to patents required under subsection 26B(1) (new subsection 26AE(5) refers) may be on a specified kind of data processing device or by way of an electronic submission.

#### **Item 6**

This item amends the note under subsection 26BB(1) of the Act, to insert a reference to the new section 26AB to make clear that medicines listed under the new section 26AE must:

- contain only permitted ingredients; and
- meet the requirements associated with their use in listed medicines.

#### **Item 7, 8 and 9**

A medicine listed in the Register under the new section 26AE will be subject to a number of conditions. Breach of a condition of listing by the sponsor can result in the cancellation of the listing from the Register.

Section 28 provides for conditions of registration or listing to be applied to medicines entered in the Register. There are three kinds of conditions that will apply to medicines listed under the new section 26AE:

- conditions that automatically apply to all medicines from the time of inclusion in the Register – these are the same as for all medicines (registered and listed) included in the Register
- additional automatic conditions that apply only to listed medicines from the time of listing in the Register; and
- discretionary conditions that the Secretary may apply to a medicine at any time after the medicine is listed or registered in the Registered.

Items 7 and 8 provide for amendments to subsection 28(5B) to allow for conditions that require each step in the manufacturing process to be carried out by persons who either hold a GMP licence, a GMP certification or who are exempt from such requirements. These conditions will apply automatically to all medicines that are listed in the Register under the new section 26AE.

Item 9 inserts subsection 28(8) to provide a condition of listing that the sponsor must hold evidence, at all times while the medicine remains listed, to support the product indications and provide this information to the Secretary upon request.

These automatic conditions are consistent with the conditions that apply to medicines listed under section 26A.

### **Items 10 and 11**

Items 10 and 11 amend section 28A to provide for the sponsor of a medicine listed in the Register under section 26AE to make an application to the Secretary for a certification that the manufacturing and quality control procedures of a step in the manufacture of the medicine carried out outside Australia are acceptable. These provisions will normally apply where the person in relation to whom a medicine is listed in the Register changes its overseas manufacturer from those assessed during the listing process and are consistent with current arrangements for medicines listed under section 26A.

### **Items 12 and 13**

#### **Items 12 and 13**

Section 29D provides for the suspension of the listing or registration of a medicine from the Register. Medicines may be suspended rather than cancelled where there is a potential risk to public health if the goods continue to be included in the Register, but the Secretary is satisfied that the sponsor will, within the period of suspension, be able to take steps to ameliorate this risk.

Once suspended, the goods are taken not to be included in the REGISTER while the suspension has effect. The therapeutic good cannot be imported, manufactured or exported from Australia by the sponsor for the duration of the suspension. The Secretary can revoke or extend a suspension.

Items 12 and 13 amend paragraph 29D(1)(b) to provide for the circumstances when the Secretary may suspend the listing of a medicine included in the Register under the new section 26AE. These are where the Secretary is satisfied that there are grounds for immediately cancelling the listing under the new paragraph 30(1)(ea) and new subsection 30(1D) (items 14 and 16 below refer).

### **Items 14, 15, 16, 17 and 18**

The Act provides for cancellation provisions that apply to all medicines (registered and listed). There are also a number of grounds for cancellation relating specifically to listed medicines. These items provide for the specific circumstances when the Secretary may cancel a medicine listed in the Register under the new section 26AE.

Consistent with current arrangements for medicines listed under section 26A, there will be circumstances where the Secretary can cancel a medicine from the Register immediately and other circumstances where the Secretary can only cancel a medicine from the Register after giving the sponsor notice of the intention to do so and inviting submissions from the sponsor.

Item 14 inserts paragraph 30(1)(ea) to empower the Secretary to immediately cancel a medicine listed in the Register under the new section 26AE in certain circumstances relating to certifications made during the listing process. These circumstances are the same as for medicines listed under section 26A under paragraph 30(1)(e) and include:

- that the medicine is ineligible for listing under the new section 26AE
- the medicine contains an ingredient that is not permitted to be used in a listed medicine
- the medicine does not comply with a requirement relating to the use of an ingredient permitted for use in a listed medicine
- if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has not been carried out by a person who is the holder of a licence to carry out that step
- the medicine contains an ingredient that is prohibited from importation
- the Secretary has not certified that all steps in the manufacture of the medicine carried out outside Australia are acceptable
- the medicine includes an ingredient of animal origin and the Secretary has not previously certified the safety of that ingredient.

Item 15 amends subsection 30(1A) to provide for immediate cancellation of a medicine listed in the Register under the new section 26AE, if the medicine is ineligible for listing, is exempt, or there has been a serious breach of the requirements relating to advertising applicable under Part 5-1 of the Act, the regulations or the Therapeutic Goods Advertising Code.

Item 16 inserts a new subsection 30(1D) to empower the Secretary to immediately cancel a medicine listed in the Register under the new section 26AE if she or he has given a notice to the medicine sponsor, under section 31, requesting information or documents about specific matters and the person fails to give that information to the Secretary within the time frame specified in the notice

In relation to the above circumstances, the Secretary is not required to give the person who is adversely affected by the decision (the person who is given a notice of the decision), a prior opportunity to respond to the cancellation. This is because the circumstances, particularly

those set out in paragraph 30(1)(e), are either very serious and require an immediate response to prevent or reduce the risk to public health or are such that listing of medicine in the Register is no longer appropriate or necessary.

Item 17 inserts paragraph 30(2)(bab) to empower the Secretary, by written notice given to the sponsor, to cancel a medicine listed in the Register under the new section 26AE in certain circumstances relating to certifications made during the listing process. These circumstances are the same as for medicines listed under section 26A and include the following:

- it appears to the Secretary that the quality safety, or presentation of the medicine is unacceptable
- the medicine does not comply with an applicable advertising requirement under Part 5-1 of the Act or under the regulations
- the sponsor does not hold evidence showing that the medicines specifications are maintained under the conditions set out on the medicine's label until the medicine's expiry date
- the sponsor no longer holds information or evidence to support each indication and claim made for the medicine
- the sponsor has failed to nominate all manufacturers involved in the manufacture of the medicine
- the sponsor doesn't have written agreements with the medicines manufacturers
- information included in or with the application is incorrect
- any other matters prescribed by the regulations.

Subsection 30(3) requires the Secretary, before cancelling the entry, to inform the person in writing that the Secretary intends to cancel the entry and provide the person with a reasonable opportunity, to respond to the notice. Subsection (4) requires the Secretary to have regard to any submissions before a decision is made.

Item 18 amends paragraph 30(5)(a) to make clear that the cancellation of a medicine under the new subsection 30(1D) (item 16 refers) takes effect on the day the notice of cancellation is given to the sponsor of the medicine.

Consistent with the current arrangements for registered and listed goods, a decision under section 30 (to cancel the listing of a medicine either immediately or following a written notice) is a reviewable decision under section 60 of the Act.

### **Item 19 and 20**

Subsection 31(2) of the Act permits the Secretary to require a range of persons to give information or documents about specified matters relating to listed medicines or that are the subject of an application for listing in the Register. These persons include persons in relation to whom therapeutic goods are, or were at any time in the last 5 years, listed, and applicants seeking to list their goods.

Item 19 amends paragraph 31(2)(fa) to make clear that the Secretary's power under that paragraph to request information applies only in relation to the matters certified in the process of listing a medicine under section 26A.

Item 20 amends subsection 31(2) to include new paragraphs 31(2)(fab) and 31(2)(fac) to enable the Secretary to require a sponsor to provide information about:

- any of the matters covered by a certification made by the person when applying to list the medicine under the new subsection 26AB(2);
- the efficacy of the goods for the purposes of which they are intended to be used.

This will enable the Secretary to request clarification or additional information where there is insufficient information for the evaluator to assess the medicine.

These arrangements are the same as those that currently apply to medicines listed under section 26A.

## **Item 21**

New paragraph 63(2)(daaaa) provides for regulations to be made to specify timeframes within which applications for new medicines assessed under section 26AE must be decided.

## **SCHEDULE 4 – Preliminary assessment of applications**

### ***Therapeutic Goods Act 1989***

This Schedule contains amendments to the Act to clarify and more accurately reflect the current administrative practices for considering applications to register and list goods on, and include biologicals and medical devices in, the Australian Register of Therapeutic Goods (the Register). The amendments reflect, for example, the administrative practice of considering whether an application to register a medicine has met certain ‘preliminary’ requirements. The requirements for which the Act will provide include that the application has been made in accordance with a form approved in writing by the Secretary (or such other approved manner) for the relevant class of therapeutic goods.

Sponsors will be notified in writing when this process has concluded and of the outcome of this assessment. If the Secretary is not satisfied, for example, that the applicant has used the approved form for the relevant class of therapeutic goods, he or she will reject a registration application.

This preliminary assessment process enables effective management of resources by government in the review of products and creates certainty for sponsors. A full evaluation process represents a considerable expenditure of resources. Because evaluation resources are finite, a requirement that an inaccurate or deficient application must nevertheless be fully evaluated necessarily means that other applications would be completed more slowly than would otherwise have been the case.

The clarifications are in response to the decision of the Federal Court in *Nicovations Australia Pty Ltd v Secretary of the Department of Health* [2016] FCA 394 that found that the process of the Department of Health (through the TGA) was not consistent with present section 23 of the Act.

Reflecting the fact these amendments confirm current administrative process, they will not impose any additional cost or administrative burden on sponsors and will provide clarity for sponsors.

### **Part 1 – Therapeutic goods**

#### **Item 1**

This item amends sub-paragraph 19A(1)(b)(ii) to clarify that the Secretary’s power to grant approval to a person to import or supply in Australia specified therapeutic goods may be contingent, among other things, on the Secretary’s satisfaction as to the existence of an application for registration of the goods that has passed preliminary assessment.

#### **Items 2 and 3**



These items amend paragraph 19A(2)(b) to clarify that the Secretary's power to grant approval to a person to import or supply in Australia specified therapeutic goods may be contingent, among other things, on the Secretary's satisfaction as to the existence of an application for registration of the goods that has passed preliminary assessment.

#### **Item 4**

This item inserts new paragraph 19A(1)(ba) to clarify that the Secretary's decision to grant approval to a person to import or supply in Australia specified therapeutic goods lapses if the fact that the good has passed preliminary assessment no longer applies.

#### **Item 5**

This item repeals existing section 23 and replaces it with new section 23 that provides for a person to make an application to the Secretary for registration or listing of therapeutic goods.

#### **Item 6**

This item inserts three new sections that set out the basis for the conduct of the Secretary's preliminary assessment process for applications to register therapeutic goods and to list therapeutic goods under section 26AE: sections 23A, 23B and 23C. Section 23A provides for the Secretary's power to, by notifiable instrument, specify different classes of therapeutic goods for the purposes of section 23B. It is anticipated, for example, that the different classes included in the notifiable instrument might be, for registrable goods, prescription medicines, complementary medicines and over the counter medicines. Prescription of classes by notifiable instrument gives the Secretary capacity to be flexible in its management of the classes whilst cognisant of not compromising certainty.

Item 5A also inserts new section 23B providing for specific requirements relating to applications for registration for therapeutic goods and for listing of medicines under section 26AE. Subsection 23B(1) obliges the Secretary to carry out an assessment of an application for registration of therapeutic goods including provisional registration or the listing of a medicine under section 26AE of whether the application has met the requirements set out in subsection 23B(2). It is only if, on carrying out an assessment of whether the application meets these requirements, the Secretary is satisfied that the application meets those requirements that the application *passes preliminary assessment* (subsection 23B(3)) (as defined by item 71 of Part 4 of this Schedule).

The Secretary's satisfaction as to whether the requirements have been met is a subjective state of mind, albeit formed according to law; it is for the Secretary to 'feel' a persuasion that the requirements have been met.

As mentioned, those requirements are set out in subsection 23B(2) and include that the application has been made in accordance with the form, or such other manner, approved, in writing, by the Secretary for that class of therapeutic goods (paragraph (a) and see subsection 23B(7)); that the prescribed application fee has been paid (paragraph (b)), that the application has been delivered to an office of the Department specified by the Secretary (paragraph (c)); that the application has been accompanied by information of a kind that is determined by the Secretary and in a form approved in writing by the Secretary (paragraph (d) and see subsections (9) and (10)); that an application for restricted medicine is accompanied by product information in the relevant approved form (paragraph (e) and see section (7D)); and that, if required by the Secretary, the applicant delivers a reasonable number of samples of the goods in a manner approved in writing by the Secretary (paragraph (f)).

For example, if a sponsor applies to register an over the counter medicine but the Secretary is not satisfied that the application has been made in accordance with the correct written form for the relevant specified class of therapeutic good, in this case, a prescription medicine, the application will not have passed preliminary assessment. Equally, if the Secretary is satisfied that the application has been made in accordance with the correct form for prescription medicine and it is accompanied by the kind of information determined by the Secretary for the specified class of therapeutic good, prescription medicines, such as clinical data and non-clinical data the application will have passed preliminary assessment.

If an application passes preliminary assessment, subsection (4) obliges the Secretary to give written notice to the applicant stating as much. If the application does not pass preliminary assessment subsection (6) obliges the Secretary, by written notice, to refuse the application.

Currently, the obligation in regulation 16B the *Therapeutic Goods Regulations 1990* to notify an applicant that the application has been accepted or rejected within the prescribed timeframes does not apply to applications to register medicines to which regulation 16G applies; that is where the sponsor of the application holds a registration for a medicine that contains the same active ingredient or active ingredients in the same dosage form and strength as in the application. The reason for the non-application of the regulation 16B obligation to notify is that these kinds of medicines are required to be evaluated within the same period (45 days unless other circumstances exist) as is prescribed for the Secretary to consider an application under s 9D(3) to vary information in the Register concerning a therapeutic good. Evaluation periods are otherwise 175 working days or 255 days (subregulation 16C(3)).

Accordingly, subsection 23B(5) provides that the Secretary is exempt from the obligation imposed by subsection 23B(4) if the period within which the Secretary must, under section 25, evaluate an application to register a therapeutic goods is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

Subsection (8) clarifies that an approval of a form may require or permit an application or information to be given in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission. Subsections (9) and (10) provide (respectively) for the Secretary to determine a kind of information for the application of paragraph 23B(2)(c) to a class of therapeutic goods that is specified under section 23A.

Item 5A also inserts new section 23C that, subsection 23C(1) provides, makes specific requirements relating to applications made under section 23 for listing of therapeutic goods under either section 26 or section 26A. As provided for by sections 26, 26AA, 26A and 26Ab, subsection 23C(2) sets out the requirements for such applications that include the application is made in accordance with a form approved, in writing, by the Secretary or in such other manner as is approved, in writing, by the Secretary for the purposes of paragraph 23C(a); the application is delivered to an office of the Department specified by the Secretary (paragraph 23C(b)); the prescribed application fee has been paid (paragraph 23C(c)); the applicant has delivered to the office to which the application was made such information, in a form approved, in writing, by the Secretary, as will allow the determination of the application (paragraph 23C(d)); if the Secretary so requires—the applicant has delivered to the office to which the application was made a reasonable number of samples of the goods (paragraph 23C(e)).

Subsection 23C(3) provides for the Secretary to determine forms of information for the purposes of the application of paragraph 23C(2)(d). Subsection 23C(4) clarifies an approval of a form may require or permit an application or information to be given in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission.

### **Item 7**

This item repeals existing subsection 24(1) and replaces it with new subsections 24(1) and (1A) providing (respectively) for the circumstances in which the Secretary must notify an applicant of an evaluation fee that is payable for an application for the registration of therapeutic goods under section 23 that has passed preliminary assessment and when, under subsection 24(2), such an application lapses.

### **Item 8**

This item repeals the chapeau of existing subsection 25(1) providing that the obligation on the Secretary to evaluate therapeutic goods for registration applies after the application made for registration has passed preliminary assessment.

### **Items 9 and 10**

These items make amendments to subsection 25AB(1) consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods; specifically clarifying that, among other circumstances, the obligation to notify an applicant of a decision to register a therapeutic device arises when the application to register the therapeutic device has passed preliminary assessment.

#### **Items 11 and 12**

These items make amendments to subsection 25AB(2) consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods; specifically clarifying that, among other circumstances, the obligation to notify an applicant of a decision to register a therapeutic good that is not a therapeutic device arises if the application has passed preliminary assessment.

#### **Items 13 and 14**

These items make amendments to subsection 25AC(1) consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods; specifically clarifying that, among other circumstances, the obligation to notify an applicant of a decision not to register the therapeutic goods arises if the application has passed preliminary assessment.

#### **Items 15 and 16**

These items make amendments to subsection 25B(1) consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods; specifically clarifying that, among other circumstances, the obligation to register a therapeutic device for which the applicant has given the Secretary an EC/EFTA attestation of conformity arises if the application has passed preliminary assessment.

#### **Items 17 to 21**

These items make amendments to section 26, providing for the listing of therapeutic goods, consequential on the provision, under section 23C, for the criteria for compliance of applications for listing; specifically clarifying that, among other circumstances, the obligation to list a product arises if the application complies with section 23C.

#### **Items 22 and 23**

These items make amendments to section 26AA, providing for the listing of a therapeutic device for which the applicant has given the Secretary an EC/EFTA attestation of conformity, consequential on the provision, under section 23C, for the criteria for compliance of applications for listing; specifically clarifying that, among other circumstances, the obligation to list a product arises if the application complies with section 23C.

## **Items 24 to 26**

These items make amendments to section 26A, providing for the listing of certain medicines, consequential on the provision, under section 23C, for the criteria for compliance of applications for listing; specifically clarifying that, among other circumstances, the obligation to list a product arises if the application complies with section 23C.

## **Item 27**

This item makes amendments to section 30C, providing for the circumstances in which the Secretary must consult with the Gene Technology Regulator, consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods. Item 27 replaces existing subsection 30C(1) and clarifies that the obligation to consult the Gene Technology Regulator arises if the application for registration is for a therapeutic good that contains a GM product or a genetically modified organism and the application has passed preliminary assessment.

## **Items 28 and 29**

These items make amendments to section 31 providing for the circumstances in which the Secretary may require information or documents, consequential on the provision, under section 23B, for the preliminary assessment of applications for registration of therapeutic goods.

Items 28 and 29 work together to clarify that if the application passes preliminary assessment and the ‘pre-submission planning form’, a form of a kind referred to in section 23B(2)(a), includes the number of days that the applicant chooses in which to give information or documents to the Secretary, the number of days in which the applicant is obliged to give that information or documents to the Secretary is that chosen number of days.

## **Item 30**

This item provides that the amendments made by Part 1 of Schedule 4 apply in relation to applications for registration or listing of therapeutic goods made after the commencement of sub-item 30(1). Sub-item 30(2) gives regulations made, immediately before the commencement of the sub-item, under subsection 24(1) prescribing the fee payable for evaluation of an application for registration of therapeutic goods effect as if they were made under subsection 24(1A) of the Act as inserted by Part 1 of Schedule 4.

## **Part 2 - Biologicals**

### ***Therapeutic Goods Act 1989***

### **Item 31**

This item replaces the reference to section 32DD in Note 2 with the correct reference to new section 32DDA that provides for the Secretary to approve different application forms for different classes of biologicals.

### **Items 32 to 36**

These items make amendments to section 32CO, providing for the Secretary to grant an approval for importation and supply of a biological in circumstances of shortages of biologicals or absence of substitutes on the Register, consequential on the provision, under section 32DDA for the preliminary assessment of applications for biologicals. The amendments clarify that such an approval may be made if, among other things, an application under section 32DD has been made for inclusion of the biological in the Register and the application has passed preliminary assessment.

### **Items 37 to 39**

These items make amendments to section 32DD to provide for a person to make an application to include a biological, other than a Class 1 biological, in the Register.

### **Item 40**

Item 42 inserts new section 32DDA providing for specific requirements relating to applications for inclusion of a biological in the Register. The terms of section 32DDA are similar to the terms of section 23B.

Subsection 32DDA(1) obliges the Secretary to carry out an assessment of an application for inclusion of the biological in the Register of whether the application has met the requirements set out in subsection 32DDA(2). It is only if, on carrying out an assessment of whether the application meets the specified requirements, the Secretary is satisfied that the application meets those requirements that the application *passes preliminary assessment* (subsection 32DDA(3)) (as defined by item 71 of Part 4 of this Schedule).

As mentioned in relation to section 23B, the Secretary's satisfaction as to whether the requirements have been met is a subjective state of mind, albeit formed according to law; it is for the Secretary to 'feel' a persuasion that the requirements have been met

Those requirements are set out in subsection 32DDA(2) and include that the application has been made in accordance with the form, or such form, or such other manner, approved, in writing, by the Secretary for that class of biological (paragraph (a) and see subsection 32DDA(7)); that the prescribed application fee for that class of biological has been paid (paragraph (b)), that the application has been delivered to an office of the Department specified by the Secretary (paragraph (c)); that the application has been accompanied by

information of a kind that is determined by the Secretary and in a form approved in writing by the Secretary for that class of biological (paragraph (d) and see subsections (9) and (10)); that, if required by the Secretary, the applicant delivers a reasonable number of samples of the biological in a manner approved in writing by the Secretary (paragraph (e)).

Similar examples concerning the Secretary's state of satisfaction as to those mentioned in relation to section 23B apply in relation to applications for inclusion of a biological. If an application passes preliminary assessment, subsection (4) obliges the Secretary to give written notice to the applicant stating as much. If the application has not passed preliminary assessment subsection (6) obliges the Secretary, by written notice, to refuse the application.

Consistent with rationale set out in relation to subsection 23B(5), subsection 32DDA(5) provides that the Secretary is exempt from the obligation imposed by subsection 32DDA(4) if the period within which the Secretary must, under s 32DE, evaluate an application to include a biological in the Register is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under s 9D(3) to vary an entry in the Register.

Subsection (8) clarifies that an approval of a form may require or permit an application or information to be given in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission. Subsections (9) and (10) provide (respectively) for the Secretary to determine a kind of information for the application of paragraph 32DDA(2)(c) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

#### **Items 41 and 42**

These items make amendments to subsection 32DE(1) consequential on the provision, under section 32DDA, for the preliminary assessment of applications for inclusion of a biological in the Register; specifically clarifying that, among other circumstances, the obligation to evaluate a biological arises when the application to include the biological has passed preliminary assessment.

#### **Items 43 and 44**

These items make amendments to subsection 32DF(1) consequential on the provision, under section 32DDA, for the preliminary assessment of applications for inclusion of a biological in the Register; specifically clarifying that, among other circumstances, the obligation to include a biological in the Register is conditional on the application having passed preliminary assessment.

#### **Items 45 and 46**

These items make amendments to section 32DG consequential on the provision, under section 32DDA, for the preliminary assessment of applications for inclusion of a biological in the Register; specifically clarifying that, among other circumstances, the obligation to notify a refusal to include a biological in the Register is conditional on the application having passed preliminary assessment.

#### **Items 47**

This item makes an amendment to subsection 32DH(1) consequential on the amendment to section 32DD providing for a person to make an applications to include a biological, other than Class 1 biological, in the Register.

#### **Items 48 and 49**

These items make amendments to subsection 32DI(1) consequential on the provision, under section 32DDA, for the preliminary assessment of applications for inclusion of a biological in the Register; specifically clarifying that an evaluation fee for the evaluation of the biological for inclusion in the Register is payable if an application for inclusion has been made and the application has passed preliminary assessment.

#### **Item 50**

Item 50 provides for the amendments made by Part 2 of Schedule 4 to apply in relation to applications for inclusion of a biological in the Register made after the commencement of this item.

### **Part 3 – Medical devices**

#### ***Therapeutic Goods Act 1989***

#### **Item 51**

This item amends the note to section 41E setting out what Part 4-4, Conformity assessment certificates, is about. The note now provides that a conformity assessment certificate may be required for an application to include a kind of medical device in the Register to pass preliminary assessment: see paragraph 41FDB(2)(e).

#### **Items 52 and 53**

These items repeal the notes to the headings to Division 3 of Part4-4, Suspension of conformity assessment certificates, and Division 4 of Part 4-4, Revocation of conformity assessment certificates.

#### **Items 54 and 55**



These items amend section 41FA to clarify what Division 1 of Part 4-5 is about; kinds of medical devices are usually included in the Register once an application is made together with the required certification and the application passes preliminary assessment. Some applications may be selected for audit.

#### **Item 56**

This item makes an amendment to the note at section 41FA consequential on the provision that a kind of medical device is required to pass preliminary assessments before inclusion in the Register. The reference in Note 1 to an application not being effective is replaced with a reference to the application passing preliminary assessment; specifically that a kind of medical device will not pass preliminary assessment unless that kind of device is covered by a conformity assessment certificate under Part 4-4.

#### **Item 57**

This item repeals section 41FB that presently includes a diagram as to how Division 1 applies to an application for a kind of medical device to be included in the Register.

#### **Item 58**

This item replaces existing section 41FC providing for a person to make an application to the Secretary for a kind of medical device to be included in the Register. Subsection 41FC (2) also prohibits an application from containing information that is false or misleading in a material particular. The note advises that a person might also commit an offence, or contravene a civil penalty provision, if the person makes a statement in an application that is false or misleading in a material particular. Attention is directed to sections 41FE and 41FEA.

#### **Item 59**

Similar to new sections 23B (for applications to register therapeutic goods) and 32DDA (for inclusion of biologicals in the Register), this item inserts new section 41FDB providing for specific requirements relating to applications for a kind of medical device to be included in the Register in relation to a person. Subsection 41FDB(1) obliges the Secretary to carry out an assessment of whether the requirements set out in subsection 41FDB(2) have been met in relation to the application for inclusion of the medical device in the Register. It is only if, on carrying out an assessment of whether the application meets these requirements, the Secretary is satisfied that the application meets those requirements that the application *passes preliminary assessment* (subsection 41FDB(3)) (as defined by item 71 of Part 4 of this Schedule).

As noted in relation to the equivalent provisions for preliminary assessment of applications for registration of therapeutic goods and inclusion of biologicals in the Register, the Secretary's satisfaction as to whether the requirements have been met is a subjective state of

mind, albeit formed according to law; it is for the Secretary to ‘feel’ a persuasion that the requirements have been met.

As mentioned, those requirements are set out in subsection 41FDB(2) and include that the application has been made in accordance with the form, or such other manner, approved, in writing, by the Secretary for that classification of medical device (paragraph (a) and see subsection 41FDB(5)); that the prescribed application fee for that classification of medical device has been paid (paragraph (b)), that the application has been delivered to an office of the Department specified by the Secretary (paragraph (c)); that the application has been accompanied by information of a kind that is determined by the Secretary and in a form approved in writing by the Secretary (paragraph (d) and see subsections (7) and (8)); if regulations made for the purposes of section 41EA require the manufacturer of the kind of device to have a conformity assessment certificate relating to the kind of medical device before an application under section 41FC can be made—such a certificate is in force; and that the applicant has certified the matters in section 41FD (paragraph (f)).

Similar examples concerning the Secretary’s state of satisfaction as to those mentioned in relation to section 23B apply in relation to applications for inclusion of a kind of medical device.

Unlike when an application to register a therapeutic good or to list one under section 26AE or an application to include a biological the Secretary is not obliged to notify the applicant that the application has passed preliminary assessment. The applicant will either be notified that the device has been included in the Register or that the device is selected for audit.

Accordingly, if the application has not passed preliminary assessment subsection (4) obliges the Secretary, by written notice, to refuse the application.

Subsection (6) clarifies that an approval of a form may require or permit an application or information to be given in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission.

Subsections (7) and (8) provide (respectively) for the Secretary to determine a kind of information for the application of paragraph 41FDB(2)(c) to a classification of medical device specified in the regulations for the purposes of section 41DB.

## **Items 60 and 61**

These items make amendments to subsection 41FF(1) consequential on the provision, under section 41FDB, for the preliminary assessment of applications for inclusion of a kind of medical device in the Register; specifically clarifying that, among other circumstances, the obligation to include a kind of medical device in the Register arises if the application has passed preliminary assessment and the application has not been selected under section 41FH for audit.

## **Item 62**

This item clarifies the obligation on the Secretary in subsection 41FF(2) to, on inclusion of a kind of medical device in the Register, make a certificate of inclusion available to the applicant.

## **Item 63**

This item replaces section 41FG providing that if an application under subsection 41FC(1) for a kind of medical device to be included in the Register is refused under wither subsection 41FDB(5) or 41FF(1A) the Secretary must notify the applicant in writing within 20 working days after receiving the application, of the refusal.

## **Item 64**

This item inserts new subsection 41FH(1A) clarifying that applications that have passed preliminary assessment may be selected for audit under section 41FH.

## **Item 65**

By the inclusion of ‘or documents’ in subparagraph 41FH(2)(a)(ii), this item clarifies that on selection of an application for audit the Secretary by written notice require the applicant provide both information and documents provided the Secretary is satisfied that they are relevant to the audit.

## **Item 66**

This item clarifies that a selection notice informing the applicant of the selection of its application for inclusion of a medical device in the Register must be given within 20 working days after the application is made and the prescribed fee has been paid.

## **Item 67**

This item amends subsection 41FM(1) clarifying that commencement of the inclusion of a kind of medical device in the Register is the day specified for that purpose in the certificate under section 41J or section 41FF.

## **Items 68 and 69**

These items make amendments to section 41HD, providing for the Secretary to grant an approval for importation and supply of a specified medical device in circumstances of shortages of medical devices or the absence of substitutes in the Register, consequential on the provision, under section 41FDB for the preliminary assessment of applications for kinds

of medical devices. The amendments clarify that such an approval may be made if, among other things, an application under section 341FDB has been made for inclusion of the kind of medical device in the Register and the application has passed preliminary assessment.

#### **Item 70**

Subitem 1 provides that the amendments made by this Part apply in relation to applications for inclusion of a kind of medical device in the Register, if the applications are made after the commencement of this item.

Subitem (2) provides that immediately before the commencement of this item, a form or manner for making an application had been approved under paragraph 41FC(1)(a) of the *Therapeutic Goods Act 1989*, then, immediately after the commencement of this time, the form or manner is taken to have been approved for the purposes of paragraph 41FDB(2)(a) of that Act, as inserted by this Schedule.

Subitem (3) provides that if immediately before the commencement of this item, an application fee had been prescribed for the purposes of paragraph 41FC(2)(b) of the *Therapeutic Goods Act 1989*, then, immediately after the commencement of this time, the fee is taken to have been prescribed for the purposes of paragraph 41FDB(2)(b) of that Act, as inserted by this Schedule.

#### **Part 4-consequential amendments**

##### **Item 71**

This item inserts a new definition of *passed preliminary assessment* in subsection 3(1) that makes cross references to the relevant provisions in subsections 23B(3), 23AE(3), 32DDA(3) and 41FDB(3) in which that term is specifically defined for applications for (respectively) registration, listing under the ‘new pathway’, inclusion of biologicals and inclusion of a kind of medical device in the Register.

##### **Item 72**

This inserts new paragraph (aa) to subsection 60(1A) with the effect that a preliminary assessment under section 23B, 26AE, 32DDA or 41FDB is not subject to merits review. This is appropriate for a decision that is preliminary to the evaluation the Secretary will carry out.

It remains possible for an applicant to challenge the Secretary’s preliminary assessment decision by judicial review; for example on the grounds that the Secretary failed to take into account relevant considerations, that the Secretary acted unreasonably etc. If an application for judicial review were to be successful the court would not be able to substitute its own decision on ‘preliminary assessment’; the court could require the Secretary to reconsider the preliminary assessment in accordance with administrative law requirements.

## **SCHEDULE 5 – Conformity assessment procedures and certificates**

This Schedule makes a number of changes to the Act to specify the operation and role of Australian conformity assessment bodies. These are Australian private bodies designated by the Secretary to appraise the suitability of the manufacturing process (“conformity assessment procedures”) for medical devices, and to assess whether such devices meet minimum standards of safety and performance (termed “Essential Principles”) in the Act.

The *Therapeutic Goods (2016 Measures No.1) Act 2017* amended the Act to allow for the introduction of such bodies by providing for matters relating to the making of conformity assessment body determinations, and the operation of such bodies, in the regulations. The Senate Scrutiny of Bills Committee queried the level of detail about such bodies in the Bill (that became that Act) as compared with the scope to provide for matters relating to them in regulations.. In acknowledging that feedback, the provisions in this Schedule set out a number of matters relating to Australian conformity assessment bodies in greater detail, including for example in relation to the content and duration of certificates issued by such bodies (i.e. certificates relating to a medical device manufacturer’s compliance with applicable conformity assessment procedures and essential principles), requirements for such bodies to maintain records and including a power for the Secretary to suspend such a body’s ability to operate (as an alternative to the Secretary’s current powers to vary or revoke that ability). These amendments are also designed to ensure that the Secretary has significant oversight of Australian conformity assessment bodies, particularly by making it clear that the Secretary may require such bodies to provide information or documents about their certification-related activities, and may also require information from manufacturers whose processes have been certified by an Australian conformity assessment body.

### **Item 1**

This item introduces a number of key definitions.

In particular, it introduces a definition of ‘conformity assessment document, which covers each of the three possible certificates or documents that will, as a result of this Bill, be available to authorise a medical device manufacturer’s compliance with the conformity assessment procedures and essential principles:

- a conformity assessment certificate (this is a certificate issued by the Secretary under section 41EC of the Act);
- an Australian conformity assessment body certificate (this is defined as meaning a certificate that is issued in respect of a manufacturer by an Australian conformity assessment body, as mentioned in new section 41FIA (item 24 refers)); or
- an overseas regulator conformity assessment document (this is defined as meaning a certificate or other document that is issued by an overseas regulator after that regulator has applied requirements comparable to the conformity assessment procedures to a medical device).

This item also makes a minor amendment to subsection 3(1) of the Act to provide that the term ‘overseas regulator’ has the meaning set out in new section 41BIB (item 5 below refers).

## **Item 2**

Subsection 3(6) of the Act explains that a reference in the Act to an annual registration or listing charge, or an annual charge for inclusion in the Register, is a reference to an annual charge imposed under the *Therapeutic Goods (Charges) Act 1989*. This item amends subsection 3(6) to include a reference to an annual conformity assessment body determination charge.

## **Item 3**

Section 41BA of the Act provides, as part of an overview of Chapter 4 of the Act, that the main requirements that apply to medical devices under the Act are the essential principles (which relate to the safety and performance of devices) and the conformity assessment procedures (which relate principally to having quality management systems in place in relation to the manufacture of medical devices).

This item makes a minor amendment to section 41BA of the Act, to refer also in this regard to requirements that are comparable to conformity assessment procedures (that may be applied to a medical device by an overseas regulator).

## **Item 4**

Section 41BB of the Act sets out the administrative processes under Chapter 4 of the Act. This item amends section 41BB to include an additional process in this regard, by referring to the making of conformity assessment body determinations.

## **Item 5**

This item introduces new section 41BIA to Division 2 of Part 4-1 of the Act, with the principal effect that a requirement that is comparable to a conformity assessment procedure will be taken not to have been applied to a medical device by an overseas regulator if there has been a contravention of the requirement, and the requirement relates, wholly or partly, to the device or its manufacture.

However, new subsection 41BIA(2) makes it clear that this will not apply for the purposes of Chapter 4 of the Act (other than Part 4-11 of Chapter 4) if the quality management system applied in the manufacture of the device complies with one or more conformity assessment standards (these are made under Division 2 of Chapter 4 of the Act) and the contravention is only in respect of a part of the requirement to which the conformity assessment standard in question relates.

This item also introduces new section 41BIB to Division 2 of Part 4-1 of the Act, with the principal effect that the Secretary will have the power to make a notifiable instrument determining bodies to be overseas regulators for the purposes of the Act. In doing so, the Secretary must, in particular, be satisfied that the overseas body is responsible for applying,

outside Australia, requirements to medical devices that are comparable to the conformity assessment procedures applying in Australia under the Act. The Secretary may determine a body to be an overseas regulator by, for example, referring to a designation, recognition, approval or authorisation (however described) of the body by one more countries (new subsection 41BIB(3) refers).

#### **Item 6**

Subsection 41EC(3) of the Act sets out a range of matters that the Secretary must consider when deciding whether or not to issue a conformity assessment certificate - for example, whether the applicant or a person who makes or participates in making decisions that affect the whole or a substantial part of the applicant's affairs (a manager) has, in the past 10 years, breached a condition of a conformity assessment certificate or had a conformity assessment certificate suspended or revoked (subparagraphs 41EC(3)(a)(viii) and (ix), respectively).

This item amends subparagraphs 41EC(3)(a)(viii) and (ix) of the Act, to make it clear that, in addition to this requirement, the Secretary must also consider whether the applicant or a manager of the applicant has, in the past 10 years, breached a condition of a certificate issued by an Australian conformity assessment body or a document issued by an overseas regulator after the regulator has applied comparable requirements to the conformity assessment procedures, or has had such a certificate or document suspended or revoked.

#### **Item 7**

Section 41EE of the Act sets out the steps that the Secretary must take after making a decision as to whether or not to issue a conformity assessment certificate and requires the Secretary, when issuing such a certificate, to specify whether the certificate covers all of a manufacturer's devices or only certain such devices (conformity assessment certificates relate to the manufacture of medical devices and can signify that relevant quality management systems have been applied to a device, that a device complies with the essential principles and that the device meets other requirements relating to applicable conformity assessment procedures).

This item amends section 41EE of the Act, to require that a conformity assessment certificate must also contain any other information prescribed by the regulations for the purposes of new subsection 41EE(3).

#### **Items 8 and 9**

Section 41EF of the Act deals with the duration of conformity assessment certificates issued by the Secretary under Division 1 of Part 4-4 of the Act. Under current subsection 41EF(2) of the Act, a conformity assessment certificate has effect until the end of the period (if any) specified in the certificate.

Item 8 amends subsection 41EF(1) of the Act to make it clear that a conformity assessment certificate must specify the period for which it is to be in force, and that this period must be no longer than 5 years – the latter requirement is designed to more closely align with Europe

(which requires manufacturers to seek re-certification after a maximum of 5 years) and to ensure appropriate oversight and re-examination of a manufacturer's processes after that period.

Item 9 amends paragraph 41EF(2)(b) of the Act, with the principal effect of making it clear that a conformity assessment certificate has effect at all times until the end of the period specified in the certificate or, if the Secretary extends this period, until the end of any such period of extension (unless the certificate is suspended or revoked).

#### **Item 10**

This item also amends section 41EF of the Act, to allow the Secretary to extend a period of duration specified in a conformity assessment certificate, for a single period of no longer than 12 months. The Secretary must give notice of any such extension to the manufacturer and may give notice to the applicant for the certificate, if not the manufacturer).

#### **Item 11**

Section 41ET of the Act lists certain circumstances in which the Secretary may, by written notice, revoke a conformity assessment certificate including if the holder of the certificate or a person who makes or participates in decisions that affect the whole or a substantial part of the applicant's affairs (a manager) has breached a condition of a conformity assessment certificate or had a conformity assessment certificate suspended or revoked (paragraphs 41ET(1)(e)(viii) and (ix), respectively).

This item amends subparagraphs 41ET(1)(e)(viii) and (ix) of the Act, to make it clear that the power of the Secretary to revoke a conformity assessment certificate under these grounds also includes where a holder of a conformity assessment certificate, or a manager of such a holder, has breached a condition of an Australian conformity assessment body certificate or an overseas regulator conformity assessment document, or has had such a certificate or document suspended or revoked.

#### **Item 12**

This item makes a minor amendment to clarify subparagraphs 41EWA(4)(b)(i) and (ii) by removing the reference in each of those subparagraphs to "kind of". This reflects that conformity assessment body determinations will relate to a category or categories of medical device or conformity assessment procedure; they are not in relation to kinds of medical device or kinds of conformity assessment procedure.

#### **Item 13**

This item amends section 41EWA of the Act to require the Secretary to assign a unique identification number to every conformity assessment body determined by the Secretary under the regulations. This item also requires the Secretary to publish a list of such conformity assessment bodies, and enables the Secretary to also publish other information



relating to such bodies that is relevant to conformity assessment body determinations or to such bodies' certification activities.

#### **Item 14**

This item makes a minor amendment to section 41EWA of the Act, to include a note after subsection 41EWA(5) highlighting that a breach of a condition of a conformity assessment body determination may be an offence under subsections 41MN(10)-(12) (item 48 below refers).

#### **Item 15**

This item amends section 41EWA of the Act, to allow the regulations to set out what the effect would be for an Australian conformity assessment body certificate issued by an Australian conformity assessment body where the body ceases to carry on its certification-related activities.

#### **Item 16**

Subsection 41EWA(7) of the Act currently allows the regulations to make provision for and in relation to empowering the Secretary to vary or revoke a conformity assessment body determination. This item amends subsection 41EWA(7) of the Act to allow the Secretary to suspend a determination, principally to provide greater flexibility by providing this option as an alternative to revocation (this is consistent with other comparable powers in the Act where powers to suspend provide an alternative to cancellation for the same conduct).

#### **Item 17**

This item introduces a new subsection 41EWA(7A) to make it clear that if, under the regulations, the Secretary suspends a conformity assessment body determination, any conditions applying to the determination under regulations made for the purposes of subsection 41EW(5) of the Act will continue to apply during the suspension.

#### **Item 18**

##### **New section 41EWB**

This item introduces a new section 41EWB to the Act, with the principal effect of requiring that a conformity assessment body certificate issued by an Australian conformity assessment body to a medical devices manufacturer specify whether it covers all devices manufactured by the manufacturer, or only specified such devices.

New section 41EWB also requires these certificates to include any other information prescribed for the purposes of new subsection 41EWB(2), and makes it clear that a certificate issued by an Australian conformity assessment body may be subject to conditions specified in the certificate.

##### **New section 41EWC**

This item also introduces a new section 41EWC to the Act, with the principal effect that an Australian conformity assessment body certificate commences on the day specified for that purpose in the certificate, and has effect at all times unless suspended or revoked by the body or until the end of the period specified in the certificate (this period must not be more than 5 years) or, if the body extends this period, until the end of any such period of extension. Subsection 41EWC(3) allows such bodies to extend the period for a which an Australian conformity assessment body certificate may be in force, for a single period of extension of no more than 12 months. If an Australian conformity assessment body extends a manufacturer's certificate, it must notify the manufacturer of the extension (subsection 41EWC(6) refers).

### **New section 41EWD**

This item also introduces a new section 41EWD to the Act, with the principal effect of requiring Australian conformity assessment bodies to maintain certain records relating to their certification activities and the certificates that they issue.

If a body is required by a condition prescribed in the regulations for the purposes of subsection 41EWA(5) of the Act to keep records relating to their certification activities (such records could include, for example, records relating to a body's issuing of conformity assessment certificates), they must keep such records at all times while they remain an Australian conformity assessment body. In addition, where a body ceases to be an Australian conformity assessment body, they must, under new subsection 41EWD(2), retain records relating to their certification activities for 15 years after they have ceased to be such a body.

This item also introduces an offence for where an Australian conformity assessment body contravenes an applicable requirement under new section 41EWD, with a maximum penalty of 1,200 penalty units, and an equivalent strict liability offence for the same conduct with a maximum penalty of 300 penalty units.

These requirements are similar to those which Australia has agreed to under the Medical Devices Single Audit Program, an international regulatory program which Australia participates in together with the United States, Canada, Japan and Brazil, and are also similar to the requirements for keeping such records in the European Union.

### **Item 19**

Section 41F of the Act sets out what Part 4-5 of the Act is about – being, the inclusion of kinds of medical devices in the Register if they comply with the essential principles and if conformity assessment procedures have been applied to them.

This item makes a minor amendment to section 41F to refer also to comparable requirements to the conformity assessment procedures, in this context.

### **Item 20**

Section 41FD of the Act requires persons who apply to include a kind of medical device in the Register to certify as to a range of matters relating to their product including, at paragraph

41FD(f), that an appropriate conformity assessment procedure has been applied to devices of that kind. Conformity assessment is the examination of manufacturing practices and procedures to ensure that medical devices that have been manufactured comply with applicable essential principles, which relate to the safety and performance of medical devices.

This item substitutes a new paragraph 41FD(f), with the effect of allowing applicants the option of certifying that either:

- the conformity assessment procedures prescribed in the regulations for the purposes of section 41DA of the Act have been applied to devices of that kind; or
- requirements that are comparable to those conformity assessment procedures have been applied to devices of that kind by an overseas regulator determined by the Secretary under new section 41BIB of the Act.

### **Item 21**

This item makes a minor, editorial amendment to subparagraph 41FD(g)(i), to reflect the changes made by item 20 above.

### **Item 22**

This item also amends section 41FD of the Act to substitute a new note under that section, the principal effect of which is to refer readers of the Act to new section 41BIA in relation to applying requirements comparable to conformity assessment procedures.

### **Item 23**

This item introduces a new section 41FDA to the Act, with the principal effect of requiring an applicant to state, in relation to the matters covered by paragraph 41FD(f) of the Act (noting that item 20 above introduces a new paragraph 41FD(f) to the Act), that their certification of those matters is based on either: a conformity assessment certificate issued by the Secretary, an Australian conformity assessment body certificate or an overseas regulator conformity assessment document. In each case, the certificate or document must be in force.

### **Item 24**

This item substitutes a new section 41FIA of the Act, with the main effect of clarifying that:

- if the Secretary selects an application for the inclusion of a kind of medical device in the Register for audit (under section 41FH of the Act); and
- the applicant has a certificate issued by an Australian conformity assessment body in respect of devices of that kind; and
- the conformity assessment body determination for the body that issued the certificate is limited, in that it only relates to particular categories of devices or conformity assessment procedures;

the Secretary may have regard to the certificate when auditing the application, provided the certificate is consistent with the scope of the issuing body's determination.

### **Item 25**

This item amends section 41FN of the Act, with the effect that it is a condition of the inclusion of a kind of medical device in the Register that, if requirements comparable to the conformity assessment procedures have been applied to the kind of device by an overseas regulator, the sponsor has available sufficient information to substantiate that those requirements have been applied to the kind of device by the overseas regulator.

### **Item 26**

This item also amends section 41FN of the Act, with the effect that it is a condition of the inclusion of a kind of medical device in the Register that, if requirements comparable to the conformity assessment procedures have been applied to the kind of device by an overseas regulator, the sponsor will give the manufacturer of the kind of device information relevant to the manufacturer's obligations under those comparable requirements.

### **Item 27**

Section 41G of the Act sets out, in brief, what Part 4-6 of the Act is about – being, the suspension and cancellation of kinds of medical devices from the Register, including for example where a conformity assessment certificate that relates to the kind of device is suspended. This item would make a minor amendment to section 41G to reflect that this grounds of suspension/cancellation may also apply where a certificate issued by an Australian conformity assessment body, or where a document issued by an overseas regulator, is suspended.

### **Item 28**

This item substitutes a new heading for Subdivision B of Division 1 of Part 4-6 of the Act, to make it clearer that Subdivision B is concerned with the power of the Secretary to suspend a kind of medical device from the Register if the conformity assessment document relating to the kind of device is also suspended.

### **Item 29**

This item substitutes a new heading for section 41GF of the Act, to reflect the amendments to be made by item 30 below.

### **Item 30**

This item introduces new section 41GFA to the Act, with the principal effect of enabling the Secretary to suspend a kind of medical device from the Register if, principally:

- an Australian conformity assessment body certificate that applies to the kind of device is suspended by the body; or
- an overseas regulator conformity assessment document that applies to the kind of device is suspended by the overseas regulator.

Before suspending a kind of device from the Register under section 41GFA, however, the Secretary must inform the sponsor of the device of the proposed suspension and give them a reasonable opportunity to make submissions on that proposal, and may not make a decision in relation to the proposed suspension until taking any such submissions into account.

The Secretary must also publish, on the Department's website, the details of any suspension as soon as practicable after any exercise of suspension powers under the new provision.

Enabling the Secretary to suspend a kind of device from the Register in these circumstances complements, and ensures consistency with, the Secretary's existing power in section 41GF of the Act to suspend a device if a conformity assessment certificate issued by the Secretary has been suspended.

### **Item 31**

This item makes a minor amendment to subsection 41GG(1) of the Act, which deals with the duration of a suspension of a kind of medical device from the Register, to reflect the introduction of new section 41GFA by item 30 above.

### **Item 32**

This item makes a minor amendment to subsection 41GH(1) of the Act, which sets out when the Secretary must revoke the suspension of a kind of device from the Register, to reflect the introduction of new section 41GFA by item 30 above.

### **Item 33**

This item also amends section 41GH of the Act, to introduce a new subsection 41GH(1A) to the Act, with the principal effect of providing the Secretary with a new discretionary power to revoke the suspension of a kind of medical device from the Register, if the following apply:

- the kind of device was suspended under new section 41GFA of the Act (i.e. where the device was suspended because a certificate issued by an Australian conformity assessment body, or a document issued by an overseas regulator, in relation to the kind of device, has been suspended); and
- the sponsor of the kind of device provides the Secretary with a replacement conformity assessment document in relation to the kind of device (i.e. either a conformity assessment certificate issued by the Secretary, a certificate issued by an Australian conformity assessment body or a document issued by an overseas regulator); and
- the Secretary is satisfied that there are no other grounds for suspending the kind of device.

### **Item 34**

This item makes a minor editorial amendment to subsection 41GH(2) of the Act, to reflect the changes made by item 33 above.

### **Item 35**

This item makes a minor editorial amendment to paragraph 41GN(1)(f) of the Act, to accommodate the changes made by item 37 below.

### **Item 36**

This item repeals the note under paragraph 41GN(1)(f) of the Act.

### **Item 37**

This item amends section 41GN of the Act, which sets out that the Secretary may cancel the inclusion of a kind of medical device from the Register in specified circumstances, to add a number of new grounds of cancellation – being, where:

- a conformity assessment document applying to the kind of device expires;
- an Australian conformity assessment body certificate applying to the kind of device is revoked by the body; and
- an overseas regulator conformity assessment that applies to the kind of device is revoked by the overseas regulator.

### **Item 38**

Section 41J of the Act sets out what Part 4-8 of the Act is about – being, the power of the Secretary to seek information or documents relating to the application of conformity assessment procedures, compliance with the essential principles and the distribution of (and others matter relating to) medical devices that are exempt from the requirement to be included in the Register.

This item makes a minor amendment to section 41J of the Act, to include a reference to requirements comparable to the conformity assessment procedures.

### **Item 39**

This item amends section 41JA of the Act, with the principal effect of making it clear that a person who is a holder of, or who was a previous holder of, a certificate issued by an Australian conformity assessment body, is a person that the Secretary may require information or documents from under section 41JA.

### **Item 40**

This item amends paragraph 41JA(1)(f) of the Act, with the effect that the Secretary may, under section 41JA, require the provision of information or documents from a person covered by paragraphs 41JA(1)(a) – (da) about whether comparable requirements have been applied to the person's devices by an overseas regulator.

### **Item 41**

This item introduces new subsection 41JA(1E) to section 41JA of the Act, to allow the Secretary to require an Australian corporation that has been an Australian conformity assessment body to provide specified information or documents relating to its certification-

related activities as such a body, or its compliance with any conditions applicable to it under subsection 41EWA(5) of the Act.

#### **Item 42**

Subsection 41JB(3) of the Act sets out that it is an offence if a person (other than an applicant for a conformity assessment certificate or for the inclusion of a device in the Register) is given a notice to provide information or documents under section 41JA of the Act and fails to do so. This item amends subsection 41JB(3) to make it clear that this offence also covers an Australian conformity assessment body that fails to comply with a notice to provide information or documents under new subsection 41JA(1E).

#### **Item 43**

Section 41KA of the Act sets out a number of circumstances in which the Secretary may impose requirements relating to the recall of medical devices. This item amends section 41KA(1), with the effect that the Secretary may take action under section 41KA if neither the conformity assessment procedures nor requirements comparable to such procedures (in the case of the latter, by an overseas regulator), have been applied to a kind of medical device.

#### **Item 44**

Section 41M of the Act sets out what Part 4-11 of the Act is about – being, offences and civil penalty provisions aimed at ensuring compliance with the essential principles, conformity assessment procedures and the requirement to include medical devices in the Register (unless exempt under the Act). This item makes a minor amendment to section 41M to also include a reference to requirements comparable to conformity assessment procedures that are applied by an overseas regulator.

#### **Item 45**

This item introduces new subsection 41MG(3) to the Act, with the principal effect of making it clear that the offences and civil penalty provision set out in sections 41ME (offences for manufacturers who fail to apply conformity assessment procedures), 41MEA (civil penalty for manufacturers who fail to apply conformity assessment procedures) and 41MF (offences for sponsors who fail to apply conformity assessment procedures) do not apply where requirements comparable to the conformity assessment procedures have been applied to a kind of device by an overseas regulator.

#### **Item 46**

This item amends paragraph 41MH(a) of the Act, with the effect that the offence in section 41MH for making a statement that is false or misleading in a material particular in or in connection with a declaration by a manufacturer that conformity assessment procedures have been applied to a medical device may also apply in the case of a manufacturer who makes such a statement in or in connection with a declaration that requirements comparable to the conformity assessment procedures have been applied to the device by an overseas regulator.

#### **Item 47**

This item makes equivalent changes to the above in respect of the civil penalty provision in section 41HA of the Act that relates to the same conduct as that covered by section 41MH of the Act.

#### **Item 48**

Consistent with the apex of offences regime being consistently introduced to the Act by the amendments in Schedule 7 of this Bill, this item amends section 41MN of the Act to include the following new offences:

- where an Australian conformity assessment body does an act or omits to do an act that breaches a condition of their conformity assessment body determination, and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person, with a maximum penalty of 20,000 penalty units;
- where an Australian conformity assessment body does an act or omits to do an act that breaches a condition of their conformity assessment body determination (i.e. without the above harm element), with a maximum penalty of 5,000 penalty units; and
- where an Australian conformity assessment body does an act or omits to do an act that breaches a condition of their conformity assessment body determination (with no harm element), where the offence is an offence of strict liability and the maximum penalty is 500 penalty units.

These penalty levels reflect in particular that Australian conformity assessment bodies are corporations, not individuals (subsection 41EWA(2) of the Act refers) and that, accordingly, it is important to ensure that maximum penalty levels reflect the seriousness of the offence and are appropriate and adequate to deter or address worst case offences.

In particular, it is important to note that these bodies will play a critical role in public health in terms of the safety and performance of medical devices produced by manufacturers whose processes have been certified by an Australian conformity assessment body. If, for example, a body were to breach a condition of their determination by not alerting the Secretary to a serious problem they were aware of with a medical device covered by one of their certificates, this could have quite serious public health consequences if the device continued to be used by patients.

#### **Item 49**

This item amends section 41MNA of the Act to include an equivalent civil penalty provision in respect of the same conduct as covered by the above offences – where an Australian conformity assessment body does an act or omits to do an act, and the act or omission breaches a condition of their conformity assessment body determination. The maximum penalty is 50,000 penalty units. As with the above offences for the same conduct, this maximum penalty reflects both that the bodies will be corporations, and the seriousness of the conduct in question in relation to public health (the human rights compatibility statement



also addresses the maximum penalty level of this civil penalty offence in the human rights law context).

### **Items 50 and 51**

Under subsection 41MP(1) of the Act, a medical devices sponsor may commit an offence if they know that particular information is covered by subsection 41MP(2) of the Act and they fail to give that information to the Secretary within the prescribed period.

These items amend paragraph 41MP(2)(d) and subparagraph 41MP(2)(d)(ii) of the Act, with the effect of making it clear that information covered by subsection 41MP(2) will include information indicating that a document issued by an overseas regulator in relation to the application of comparable requirements to the conformity assessment procedures has been restricted, suspended or revoked or is no longer in effect.

### **Items 52 and 53**

These items make equivalent changes to the above in respect of the civil penalty provision in section 41MPA of the Act that relates to the same conduct as that covered by section 41MP of the Act.

### **Item 54**

Section 43 of the Act sets out that an annual charge is payable by the person in relation to whom therapeutic goods are registered, listed or included in the Register, and that an annual licensing charge is payable by a holder of a manufacturing licence. This item amends section 43 to make it clear that an annual charge (an ‘annual conformity assessment body determination charge’) is also payable by an Australian corporation that is the subject of a conformity assessment body determination.

### **Item 55**

Section 44 of the Act sets out when an annual charge that is payable must be paid by. This item amends section 44 to set out when an annual conformity assessment body determination charge for a financial year becomes payable. Principally, this will be on the 28<sup>th</sup> day after the determination came into force (in relation to the financial year in which the determination came into force) or, for subsequent financial years, on October 1 of that financial year or on any such other date as is prescribed (subject to the Secretary’s power under subsection 44(3) of the Act to specify a later date for when a charge becomes payable for a person).

### **Item 56**

This item amends subsection 44(3) to make it clear that the Secretary’s power to specify, by written notice, a later date for when an annual charge becomes payable for a person under subsections 44(1) or (2) of the Act also applies in respect of when an annual charge for a conformity assessment body determination would otherwise be payable under new subsection 44(2A).

### **Item 57**

Section 44B of the Act provides that an unpaid annual charge can be recovered as a debt due to the Commonwealth if unpaid 28 days after the day on which the charge becomes payable. This item amends section 44B to make it clear that this provision also applies in respect of an annual charge for a conformity assessment body determination that remains unpaid for that same period.

### **Item 58**

Section 45 of the Act provides for the continued existence of the Therapeutic Goods Administration Account, a special account for the purposes of the *Public Governance, Performance and Accountability Act 2013* (subsection 45(2) refers). Paragraph 45(3)(a) provides that there must be credited to the Account amounts equal to amounts received by the Commonwealth by way of annual registration and listing charges and annual licensing charges. This item amends paragraph 45(3)(a) to also include a reference to annual conformity assessment body determination charges in this context.

### **Item 59**

This item amends section 46A of the Act, which deals with the powers of an authorised person to search certain premises to monitor compliance with the Act, to make it clear that such premises include the premises of a person who has been issued with an Australian conformity assessment body certificate, or who has applied for such a certificate.

### **Item 60**

This item amends the table of offences in section 53A of the Act, with the effect that if a jury acquits a person of an offence against new subsection 41MN(10) (breach of a condition of a conformity assessment body determination that has resulted in, or that will result in or that is likely to result in, harm or injury to a person), but is satisfied beyond reasonable doubt of facts that prove the person is guilty of the offence in new subsection 41MN(11) (relating to the same conduct, but without any harm element), then the jury may convict the person of the latter offence.

### **Items 61-63**

Subsection 54B(1) of the Act has the effect that an executive officer of a body corporate commits an offence if the body corporate commits an offence against the Act that is covered by section 54BA of the Act (which lists a number of particularly serious offences against the Act) and the officer knew that the offence would be committed and was in a position to influence the conduct of the body corporate in relation to the commission of the offence and failed to take all reasonable steps to prevent the offence being committed.

Item 63 amends section 54BA of the Act, which lists offences for which executive officers may be personally liable for the purposes of paragraph 54B(1)(a) of the Act, to add the new offence introduced by item 48 in relation to where an Australian conformity assessment body

does an act or omits to do an act that breaches a condition of their conformity assessment body determination, and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person (new subsection 41MN(10)).

Given the seriousness of this offence and the potential consequences for public health, the addition of this offence in this context is appropriate and consistent with the principles agreed to by the Council of Australian Governments in 2009 as the basis on which personal liability for corporate fault should be imposed (these are set out in the explanatory memorandum for the Personal Liability For Corporate Fault Reform Bill 2012 (which became the Personal Liability For Corporate Fault Reform Act 2012, and commenced on 11 December 2012), available at [www.legislation.gov.au](http://www.legislation.gov.au)), particularly as an executive officer may only commit an offence under section 54B(1) of the Act where the officer knew the offence would be committed, was in a position to influence the corporation's conduct in relation to the commission of the offence and did not take all reasonable steps to avoid the commission of the offence.

Item 61 substitutes a new subsection 54B(2) of the Act, with the principal effect of making it clear that the maximum penalty for an offence by an executive officer under subsection 54B(1) of the Act, in respect of an offence by their body corporate under new subsection 41MN(10) is 5 years' imprisonment or 4,000 penalty units, or both.

Subsection 54B(3) of the Act sets out a civil penalty equivalent of subsection 54B(1) of the Act, in that it provides a civil penalty provision mechanism for executive officers of body corporates that contravene a civil penalty provision of the Act that they knew would occur, were in a position to influence the conduct of the body corporate in that regard and failed to take all reasonable steps to prevent the contravention.

Item 62 substitutes a new subsection 54B(4) of the Act, to set out a civil penalty provision for an executive officer of a body corporate that contravenes the new civil penalty provision relating to breaching a condition of a conformity assessment body determination (new section 41MNA), with a maximum penalty of 5,000 penalty units.

#### **Item 64**

This item amends section 56A of the Act (certificates to provide evidence of certain matters under the Act) to enable the Secretary or a person authorised in writing by the Secretary to certify in writing that there was no conformity assessment body determination in force in respect of a particular Australian corporation, or that a conformity assessment body determination was in force and was of general application or was limited to the extent specified in the certificate.

#### **Item 65**

This item substitutes a new subsection 61(5) of the Act, with the principal effect that the Secretary may release information that relates to Australian conformity assessment bodies (to the extent that the information relates to conformity assessment body determinations or to the certification-related activities of such bodies) to a national regulatory authority of another

country, or an international organisation, with which the Commonwealth has cooperative arrangements in place that relate to the assessment or regulation of therapeutic goods (provided that the release of that information is consistent with those arrangements).

## **Item 66**

This item sets out the following application measures:

- the amendments of section 41EC of the Act made by this Schedule apply in relation to applications under section 41EB of the Act made on or after the commencement of this item;
- the amendments of sections 41EE of the Act made by this Schedule apply in relation to conformity assessment certificates issued on or after the commencement of this item;
- the amendments of subsections 41EF(1) and (2) of the Act made by this Schedule apply in relation to conformity assessment certificates issued on or after the commencement of this item;
- new subsections 41EF(3) – (6), as added to the Act by this Schedule, apply in relation to a conformity assessment certificate issued on or after the commencement of this item and a conformity assessment certificate issued before the commencement of this item that was in force immediately before that commencement;
- the amendments of section 41ET of the Act made by this Schedule apply in relation to revocations under that section made on or after the commencement of this item (where the breach referred to in subparagraph 41ET(1)(e)(viii) (where the breach referred to in subparagraph 41ET(1)(e)(viii), or the suspension or revocation referred to in subparagraph 41ET(1)(e)(ix), occurred on or after the commencement of this item;
- the amendments of section 41FD of the Act made by this Schedule apply in relation to applications made under section 41FC of the Act on or after the commencement of this item; and
- new section 41FDA of the Act, as inserted by this Schedule, applies in relation to applications made under section 41FC of the Act on or after the commencement of this item;
- the amendments of section 41FN of the Act made by this Schedule apply in relation to kinds of medical devices included in the Register on or after the commencement of this item;
- the amendments of subsection 41JA(1) of the Act made by this Schedule apply in relation to notices given under section 41JA on or after the commencement of this item;
- the amendments of subsection 41KA(1) of the Act made by this Schedule apply in relation to supplies of medical devices on or after the commencement of this item;

- the amendments of sections 41MH and 41MHA of the Act made by this Schedule apply in relation to statements made on or after the commencement of this item;
- the amendments of sections 41MP and 41MPA of the Act made by this Schedule apply in relation to restrictions, suspensions or revocations on or after the commencement of this item (whether the certificate or other document was issued before, on or after that commencement); and
- subsection 61(5), as inserted by this Schedule, applies in relation to the release of information on or after the commencement of this item (whether the information was obtained before, on or after that commencement).

## **SCHEDULE 6 – Advertising**

### **Part 1 – Enforcement**

#### ***Therapeutic Goods Act 1989***

The Australian *National Medicines Policy* recognises the primary position of the consumer in the *Quality Use of Medicines* framework. This means that the consumer can select management options wisely; choose suitable medicines (if a medicine is considered necessary); and using medicines safely and effectively. Similar considerations apply to other therapeutic goods (such as certain medical devices) that may be appropriate for self-selection by consumers for use in the care of them or their family.

To support this position, industry should be able to provide truthful information to potential consumers about the nature and benefits of therapeutic products. They should be able to do so through responsible advertising, where this will enhance the health outcomes of the Australian people. In this context a robust and effective system for regulating advertising that provides confidence for consumers is required. The system should give consumers confidence that the claims they read and hear are well-founded, and it should provide a level playing field for industry.

Appropriate controls on advertising are required to adequately protect the public from false or misleading advertising of therapeutic goods and the consequent risks to public health. Schedule 6 amends the advertising related provisions throughout the Act to modernise the advertising framework for therapeutic goods while taking account evolving advertising practices.

In particular, these amendments

- improve consistency across regulation of advertising of different types of therapeutic goods;
- repeal the requirement for certain advertisements to be pre-approved (see Part 2);
- provide provisions to support the Department of Health (through the TGA) as the single body responsible for implementing a more transparent and efficient complaints management process about the advertising of therapeutic goods to the public; and
- broaden sanctions and penalties to deter inappropriate and misleading advertising of therapeutic goods.

The changes in Schedule 6 will be accompanied by an education program to assist industry sponsors and advertisers in understanding their obligations under the new regulatory framework so that they have the appropriate information to allow them to comply with the advertising requirements.

This Schedule provides for some specific advertising enforcement provisions. However, other sanctions provided for in Schedule 7 such as injunction and infringement notices apply generally to contraventions in the Act including the advertising of therapeutic goods.

The introduction of the tiered regime of criminal offences is intended to better tailor penalties to criminal conduct so that more serious offences resulting in or likely to cause harm or injury will attract sanctions that appropriately reflect that severity. The penalties for the offences with aggravating elements (“aggravated offences”) are significantly higher than the existing offences without the aggravating element, to reflect the fact that breaches of these provisions have resulted in, or will pose, a serious and direct threat to public health and safety.

The 100 penalty unit maximums for the new strict liability offences are considered appropriate. Although they are higher than the usual maximum for strict liability offences, this is justified because of the potential risk to public health arising from the misuse of therapeutic goods. The conduct involved in each of these offences is sufficiently serious that, if the defendant were convicted of an equivalent fault-based offence, a much higher penalty could be imposed, including a significant term of imprisonment.

### **Item 1**

Item 1 inserts a new definition of “advertise” in section 3 of the Act.

In recognition of the changing nature of “advertising” of therapeutic goods in recent years, a new definition of “advertise” in relation to therapeutic goods is provided in subsection 3(1) of the Act replacing the current definition of “advertisement”. This change is reflected in all provisions that currently refer to “advertisements” or “advertising”. Previous references to “publish” or “broadcast” have been removed as they are now redundant.

The definition of ‘advertise’ encompasses only material of a promotional character.

However, the definition is also intended to maintain a wide compass, in that, even if the material or the format of advertising can be said to promote the use or supply of relevant goods only in an indirect way, the material or format will still be an ‘advertisement’.

Further, for clarity, the definition of “advertise” makes it clear that a statement, pictorial representation or design includes where the statement, pictorial representation or design:

- is on the label of the therapeutic goods;
- is on the package in which the goods are contained;
- is on any material included in the package in which the goods are contained.

The inclusive list leave open the possibility of other examples of what it means to advertise.

Consistent with the common law, the test of whether material is intended to promote a particular product is an objective one; that is, the question is whether the material or format, ‘on its face and without reference to the actual intentions of those concerned with its circulation, publication, transmission, or dissemination’, appears to be designed or calculated to draw public attention to and to promote the supply, sale or use of the particular therapeutic good.

## **Item 2**

As a consequence of the inclusion of the word “advertise” in subsection 3(1), Item 2 repeals the definition of “advertisement”.

## **Item 3**

This item inserts a reference to ‘related body corporate’ as defined in the *Corporations Act 2001*. This reference is required in relation to proposed amendments to the cancellation provisions for goods included in the Australian Register of Therapeutic Goods (the Register) where a related corporate entity contravenes a direction or condition under subsection 42DV(1).

## **Item 4**

Item 4 adds a new subsection 21B(4), a civil penalty provision for advertising therapeutic goods that are included in the Register where the indication advertised by the person in relation to the therapeutic goods is not an indication accepted in relation to that inclusion. The contravention of subsection 21B(4) attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

## **Items 5**

Items 5 to 7 introduce a new tiered offence in relation to the advertising of an indication about therapeutic goods that are entered in the Register, and the indication communicated in the advertisement is not an indication accepted in relation to that inclusion of that particular therapeutic good in the Register.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, contravention of which could result or may result in harm or injury to the public, the amendments to section 22 introduce a new tiered offence, consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the goods has resulted in, or will result in, harm or injury to any person, or the use of the goods, if the goods were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. This high level offence attracts a higher maximum pecuniary penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 22(2));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 22(3)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 22(5) and (22(5A))).



Reflecting the definition of advertise, the offer or supply of a therapeutic good by a person to the public would be an offence, where that good is included in the Register and the indication on the label or packaging of the therapeutic good is not consistent with what is entered in the Register.

These offences must be read in conjunction with the offence provisions under section 42DL. For example, a prescription medicine cannot be advertised to the public, irrespective of whether the indication for the prescription medicine is consistent with the indication accepted in the Register in relation to that medicine or not.

### **Item 8**

Section 29D empowers the Secretary, by written notice given to a person in relation to whom therapeutic goods are included in the Register, to, in specified circumstances, suspend the registration or listing of the goods. Paragraph 29D(1)(b) provides that the Secretary may suspend the registration or listing of the therapeutic goods as provided for under subsection 29D(1) if the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e) or (f) or subsection 30(1A), (1C) or (2). Item 8 includes new paragraphs 30(1)(fa) and (fb) in this list reflecting the amendments set out in Item 9 below.

### **Item 9**

The current section 30 empowers the Secretary, by notice in writing given to a person in relation to whom therapeutic goods included in the Register, to immediately cancel the registration or listing of the therapeutic goods in the circumstances set out in subsections (1), (1A), (1C), (2) and (4), and subject to the applicable requirements set out in subsections (1B), (3), and (4).

The current paragraph 30(1)(f) empowers the Secretary under subsection 30(1), subject to the requirements set out in this subsection, to cancel the registration or listing of therapeutic goods if under the *Therapeutic Goods Regulations 1990* (the Regulations), an authority constituted by or under the Regulations gives a direction, or makes a requirement of, the person in relation to an advertisement of the goods to ensure that advertising complies with the Therapeutic Goods Advertising Code (the Advertising Code) and the person does not comply with the direction or requirement.

Item 9 includes new paragraphs (f), (fa) and (fb) in subsection 30(1) to reflect the application of new section 42DV (Item 38 refers), and to omit the reference in relation to the giving of directions or the making of a requirement by an authority constituted by or under the Regulations. The Complaints Resolution Panel (established by regulation 42R) currently has the power to give a direction or make a requirement of a person in relation to the advertising of therapeutic goods. However, the Secretary will be the single body responsible for handling of all complaints about the advertising of therapeutic goods to the public in the future.

Thus, the amendments now provide that the Secretary can cancel the registration or the listing of the therapeutic goods under subsection 30(1) if:

- the person to whom the goods are included in the Register was given a direction under subsection 42DV(1) in relation to an advertisement about the goods and the person contravenes that direction or a condition of a direction and where the Secretary was satisfied that the contravention is significant (paragraph 30(1)(f));
- if the person is a body corporate – a related body corporate of the person to whom the goods are included in the Register, contravenes a direction or a condition of a direction given to the related body corporate under subsection 42DV(1) and where the Secretary was satisfied that the contravention is significant (paragraph 30(1)(fa)); or
- there is a breach, involving the goods included in the Register, of an applicable provision of the Advertising Code or any other requirement relating to advertising applicable under Part 5-1 of the Act, and the Secretary is satisfied that the breach is significant and as a result of the breach, the presentation of the goods is misleading to a significant extent (paragraph 30(1)(fb)).

Paragraph 30(1)(fa) only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate. It provides for the cancellation of a good from the Register where the non-compliant advertising is undertaken by a related body corporate. Paragraph 30(1)(fb) reflects the current ground for cancellation of a medicine listed under section 26A previously provided for under paragraph 30(1A)(c) which is to be omitted (Item 12 refers).

#### **Item 10**

Item 10 inserts a new subsection 30(1AA) to make it clear that paragraph (1)(fb) does not apply to medicines that are listed under section 26 (medicines that are manufactured in Australia for export only, or are imported into Australia for export only). This reflects the current exclusion of paragraph 30(1A)(c) to medicines that are manufactured in Australia for export only or are imported into Australia for export only in subsection 30(1B) which is to be repealed by Item 13.

#### **Item 11**

Item 11 is a technical amendment and reflects the removal of paragraph 30(1A)(c) (Item 12 refers).

#### **Item 12**

Item 12 repeals paragraph 30(1A)(c). This ground for cancellation is now included in subsection 30(1) under paragraph (fb) (refer to Item 9).

#### **Item 13**

Item 13 repeals subsection 30(1B), as this provision is now provided for under paragraph 30(1AA) (Item 10 refers).

#### **Item 14**

Consistent with Item 9, Item 14 inserts two new paragraphs, (eaa) and (eab), to subsection 30(2) within the context of proposed cancellation with notice of registration or listing of therapeutic goods.

Paragraph 30(2)(eaa) provides for the Secretary to cancel the registration or listing of therapeutic goods where the person contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the goods. Paragraph 30(2)(eab) provides for the cancellation of a good from the Register where a related body corporate contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the goods. This provision only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate.

#### **Items 15 to 18**

Items 15 to 18 introduce a new tiered offence in relation to the advertising of a biological that is entered in the Register in relation to a particular indication, and the advertised indication is not an indication accepted in relation to the inclusion of that particular biological in the Register.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, the contravention of which may result or would result in harm or injury to a person, section 32BJ introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the biological has resulted in, or will result in, harm or injury to any person, or the use of the biological, if the biological were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 32BJ(2A));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 32BJ(2B)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 32BJ(3) and (3A)).

Thus, Item 15 inserts the high level offence provided for under subsection 32BJ(2A) and the ordinary offence provided for under subsection 32BJ(2B).

Item 16 repeals the heading for subsection 32BJ(3) whereas Item 65 repeals the penalty and substitutes a maximum penalty of 100 penalty units.

Item 17 inserts a new provision (section 32BJ(3A)) stating that the offence against subsection 32BJ(3) is an offence of strict liability.

As “advertise” encompasses a statement, pictorial representation or design on the label of the goods or in information included in or on the packaging of the biological, or any material included on the package, the offer for or the supply of a biological, including as a sample, where the biological is included in the Register with an indication visible on the label, packaging, or material included with the package of the biological, that is not an indication accepted in relation to the inclusion of the biological, would be captured within this offence.

In addition, the offences set out in subsections 32BJ(2A), (2B) and (3) must be read in conjunction with subsection 42DL(11) (Item 35 refers) that prohibits the advertising, by any means of therapeutic goods if the advertisement refers to a biological other than a reference authorised or required by an Australian government or government authority. Thus, no advertisements about biologicals can be made directly to the general public, including where the indications of the biologicals set out or referred to in the advertisement are indications accepted in the inclusion of the biological in the Register.

#### **Item 19**

Item 19 adds a new civil penalty provision, section 32BL, for advertising a biological for an indication that is not an indication accepted in relation to the inclusion of the biological in the Register. Contravention of section 32BL attracts a maximum penalty of 5,000 penalty units for an individual, and 50, 000 penalty units for a body corporate.

#### **Item 20**

Section 32GA empowers the Secretary, by notice in writing given to a person in relation to whom biologicals are included in the Register, to cancel the entry of the biologicals in the Register in the circumstances set out in paragraphs (1)(a) to (j).

Current paragraph 32GA(1)(i) empowers the Secretary, subject to the requirements set out in subsection 32GA(1), to cancel the entry of the biological in the Register if under the Regulations, an authority constituted by or under the Regulations gives a direction, or makes a requirement of, the person in relation to an advertisement of the goods to ensure that advertising complies with the Advertising Code and the person does not comply with the direction or requirement.

Current paragraph 32GA(1)(j) provides that the Secretary may immediately cancel the entry of the biological from the Register, subject to the requirements under subsection 32GA(1) if there is a breach involving a biological, of an applicable provision of the Advertising Code or any other requirements relating to advertising applicable under Part 5-1 or under the regulations.

Item 20 repeals paragraphs 32GA(1)(i) and (j) and substitutes new paragraphs (1)(i), (j) and (k) to reflect the application of new section 42DV (Item 38 refers), and to omit the reference in relation to an authority constituted by or under the regulations.

Thus, the amendments now provide that the Secretary can cancel the entry of a biological in the Register under subsection 32BJ(1) if:

- the person to whom the biological is entered in the Register was given a direction under subsection 42DV(1) in relation to an advertisement about the biological and the person contravenes that direction or a condition of a direction and where the Secretary was satisfied that the contravention is significant (paragraph 32BJ(1)(i));
- if the person is a body corporate – a related body corporate of the person to whom the biological is included in the Register, contravenes a direction or a condition of a direction given to the related body corporate under subsection 42DV(1) and where the Secretary was satisfied that the contravention is significant (paragraph 32BJ(1)(j)); or
- there is a breach, involving the biological included in the Register, of an applicable provision of the Advertising Code or any other requirement relating to advertising applicable under Part 5-1 of the Act, and the Secretary is satisfied that the breach is significant and as a result of the breach, the presentation of the goods is misleading to a significant extent (paragraph 32BJ(1)(k)).

Paragraph 32GA(1)(j) only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate. It provides for the cancellation of a good from the Register where the non-compliant advertising is undertaken by a related body corporate.

## **Item 21**

Consistent with Item 20, Item 21 inserts two new paragraphs (32GC(1)(fa and (fb)) within the context of proposed cancellation with notice of the entry of a biological from the Register.

Paragraph 32GA(1)(i) provides for the Secretary to cancel the entry of the biological from the Register where the person contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the goods. Paragraph 32GA(1)(j) provides for the cancellation of the entry of the biological from the Register where a related body corporate contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the goods. This provision only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate.

## **Item 22**

Section 41GL empowers the Secretary, by notice in writing given to a person in relation to whom a kind of medical device is included in the Register to immediately cancel the entry of

the kind of device in the Register if any of the circumstances listed in paragraphs (a) to (h) is met or occurs.

Because the Complaints Resolution Panel (established by regulation 42R of the Regulations) is being replaced by the Secretary current paragraph 41GL(g) that provides for a ground for immediate cancellation of an entry of the kind of device in the Register on a direction of the Panel is redundant and is repealed.

With the introduction of new section 42DV (Item 38), Item 22 introduces new paragraphs 42GL(g) and (ga) as grounds for the immediate cancellation of the entry of a kind of device in the Register if a person contravenes a direction or a condition of a direction given to the person under subsection 42DV(1) in relation to the kind of device and the Secretary was satisfied that the contravention is significant. Paragraph 42GL(g) applies to the person while paragraph 42GL(ga) applies if the person is a related body corporate.

Paragraph 42GL(ga) only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate. It provides for the cancellation of a kind of medical device included in the Register where the non-compliant advertising is undertaken by a related body corporate.

### **Item 23**

Item 100 omits the word ‘serious’ in the introductory sentence of paragraph 41GL(h). The use of the word ‘serious’ is redundant as subparagraph (i) already requires that the Secretary must be satisfied that the breach is significant, and subparagraph (ii) requires that as a result of the breach, the presentation of the devices of that kind is misleading to a significant extent.

### **Item 24**

Section 41GN empowers the Secretary, by notice in writing given to a person in relation to whom a kind of medical device is included in the Register, to cancel the entry of the kind of device from the Register. However, in contrast to section 41GL of the Act, the Secretary is required to inform the person in writing of the proposal to cancel the entry of the kind of device in the Register and give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed cancellation.

Section 41GN currently does not provide for a ground for cancellation where the person in relation to whom the kind of device is entered in the Register has breached advertising requirements under Part 5-1 of the Act or the Regulations, or an applicable provision in the Advertising Code. For consistency with the grounds for cancellation of the entries of kinds of medical devices set out in section 41GL, Item 24 adds new paragraphs (i), (j) and (k).

Paragraph 41GN(1)(i) provides for the Secretary to cancel the entry of the kind of medical device from the Register where the person contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the device.

Paragraph 41GN(1)(j) provides for the cancellation of the entry of the kind of medical device from the Register where a related body corporate contravenes a direction or condition given under subsection 42DV(1) in relation to an advertisement about the goods. This provision only applies to bodies corporate within the meaning of the *Corporations Act 2001*, and would not apply to family trusts or entities that are not bodies corporate.

Paragraph 41GN(1)(k) provides that the Secretary may cancel the entry of a kind of medical device from the Register in relation to a person, where either of the following has not been complied with:

- an applicable provision of the Advertising Code;
- any other requirement relating to advertising applicable under Part 5-1 or the Regulations.

## **Item 25**

Item 25 introduces a new tiered offence in relation to the advertising of a medical device that is of a kind entered in the Register in relation to a particular purpose, and the purpose communicated in the advertisement is not a purpose accepted in relation to that inclusion of that particular kind of device in the Register.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act where a contravention may result or would result in harm or injury to a person, section 41ML introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the medical device has resulted in, or will result in, harm or injury to any person, or the use of the medical device, if the medical device were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 41ML (1));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 41ML(2)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 41ML(3) and (4)).

## **Item 26**

Item 26 inserts a corresponding civil penalty provision in relation to the offences set out in section 41ML. Thus, a person contravenes section 41MLB if a person, by any means, advertises a medical device for a purpose, and that device is of a kind included in the Register; and the purpose is not a purpose accepted in relation to the inclusion of the device in the Register. Contravention of section 41MLB attracts a maximum penalty of 5,000

penalty units for an individual and a maximum penalty of 50,000 penalty units for a body corporate.

### **Item 27**

Item 27 is a consequential amendment.

The current subsection 42AC(1) provides that, subject to subsection (2), Part 5-1 of Chapter 5 of the Act does not apply to advertisements solely for therapeutic goods that have been exported or are intended exclusively for export. Subsection 42AC(2) currently specifies that section 42DKB applies to advertisements solely for therapeutic goods that have been exported, or are intended exclusively for export. Item 27 amends subsection 42AC(2) to provide that sections 42DKB, 42DLA, and 42DLC and Divisions 5 and 6 apply to advertisements or therapeutic goods that have been exported or are intended exclusively for export. Thus, although these therapeutic goods are not for supply in Australia, any advertising of these types of goods are subject to:

- a notice in the circumstances set out in subsection 42DKB(1), preventing the person apparently responsible from advertising the therapeutic goods, or causing the advertising of those therapeutic goods, in circumstances where the advertisement contains the false or misleading representation;
- directions from the Secretary under section 42DV in relation to that advertisement;
- offence and civil penalty contravention in relation to a notice under section 42DKB (ie sections 42DLA and 42DLC)
- a notice under section 42DR requesting specified information or production of documents, and the corresponding offence and civil penalty contravention for non-compliance and giving or false misleading information or document, respectively (sections 42DS, 42DT and 42DU);
- a direction under section 42DV, and the corresponding offence and civil penalty provisions (sections 42DW and 42DX)

### **Item 28**

Item 28 is a technical amendment that omits the words “about therapeutic goods” (last occurring) as those words are redundant and are already included in the definition under section 42DD of a restricted representation.

### **Item 29**

Item 29 is also a technical amendment and repeals the existing note and replacing it with a new note reflecting the changes made in the Act by the introduction of revised section 42DL and new section 42DLB (Item 35 refers).

### **Item 30**



Section 42DI empowers the Secretary, by written notice, to withdraw the approval of the use of a restricted representation. The requirements in relation to the notification are provided for under subsection 42DI(2).

Item 30 adds a new paragraph 42DI(1)(c) as an additional ground for the revocation of an approval for the use of a restricted representation, where the use of the restricted representation is permitted under subsection 42DK(1). Where an approval is replaced by a representation permitted under subsection 42DK(1), there is no longer a need to have a separate approval to use the restricted representation under section 42DF. This is necessary to ensure that a person lawfully using the restricted representation in an advertisement is not subject to conflicting conditions, or requirements applying to the use of the restricted representation under section 42DF and the permitted use under subsection 42DK(1).

### **Item 31**

Item 31 repeals section 42DK and substitutes new subsections 42DK(1) to (4).

The current section 42DK empowers the Secretary, by writing, to permit the use of specified restricted representations and specified prohibited representation in specified advertisements about specified therapeutic goods.

Section 42DD of the Act defines a restricted representation for the purposes of Part 5-1 of the Act as a representation in an advertisement about therapeutic goods that refers to a form of a disease, condition or ailment or defect identified in the part of the Advertising Code as a serious form of a disease, condition, ailment or defect. Restricted representations listed in the current Advertising Code include cardiovascular diseases, dental and periodontal diseases, diseases of joint, bone and collagen, rheumatic disease, diseases of the eye or ear likely to lead to blindness or deafness, diseases of the liver, biliary system or pancreas, and endocrine diseases and conditions that include diabetes and prostatic disease .

Regulation 6B of the Regulations for the purposes of subsection 42DJ(1) provides that the following are prohibited representations:

- representations in column 2 of an Item in part 1 of Schedule 2 about therapeutic goods in column 3 of that Item; and
- representations in Appendix 6 to the Advertising Code.

Examples of prohibited representations listed in the Advertising Code include any representation regarding abortifacient action; or any representation regarding the treatment, cure or prevention of neoplastic diseases, sexually transmitted diseases, HIV, AIDS, Hepatitis C or mental illness.

Subsection 42DK(1) empowers the Secretary, by writing, to permit the use of specified restricted representations in specified advertisements about a particular therapeutic good. Subsection 42DK(1) does not require an applications from a sponsor or advertiser for the Secretary to grant permission.

Subsection 42DK(2) empowers the Secretary, by writing, to permit the use of specified prohibited representations in specified advertisements about particular therapeutic goods. In contrast to subsection 42DK(1), subsection 42DK(2) only empowers the Secretary to permit the use of a prohibited representation if the Secretary is satisfied that the representations are necessary for the appropriate use of the goods in relation to the following circumstances: on the label of specified therapeutic goods, on the package in which therapeutic goods are contained, or any material included with the package in which specified therapeutic goods are contained. Appropriate use would include the need for the specific indication that is entered in the Register to be included on those materials.

Subsection 42DK(3) empowers the Secretary, by writing, to permit the use of specified prohibited representations in specified advertisements about specified therapeutic goods, if the Secretary is satisfied that the representations are necessary in the interests of public health. Examples of permissions that can be granted in this subsection would be advertisements about sunscreens promoting the use of these goods for protection against skin cancer.

The permissions set out in subsections (1) to (3) are not legislative instruments (refer to subsection 42DK(5)).

As the permissions under this provision may relate to multiple persons, the Secretary is required to publish a permission under this section on the Department's website so that the affected parties are informed of the scope and conditions of the permissions (refer to subsection 42DK(6)).

### **Item 32**

Item 32 repeals the current heading for section 42DKB and substitutes a new heading reflecting the new definition "advertise" under subsection 3(1).

### **Item 33**

Item 33 replace subsection 42DKB(1) reflecting the new definition of "advertise". References to the words publish or broadcast in current subsection 42DKB(1) are replaced with the word "advertising" to ensure that the dissemination or circulation of advertisements covers new and innovative approaches.

### **Item 35**

#### Section 42DL

Item 35 replaces section 42DL with a new section 42DL.

Item 35 introduces a new tiered offence in relation to the contraventions of specific requirements applying to advertisements about therapeutic goods. This provision applies to

advertisements of all therapeutic goods (medicines, biologicals, medical devices and other therapeutic goods) and generic information about therapeutic goods

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, the contravention of which may result or would result in harm or injury to a person, section 42DL introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element and a nexus element (the use of the therapeutic good in reliance on the advertisement has resulted in, or will result in, harm or injury to any person, or the use of the therapeutic good, if the therapeutic good in relation on the advertisement were used, would result or likely result, or be likely to result, in harm or injury to a person). The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 42DL(1));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 42DL(2)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 42DL(3) and (4)).

Subsections (5) to (12) specify the requirements that if contravened by a person who advertises by any means, therapeutic goods, or causes the advertising, by any means, of therapeutic goods, that person would be committing an offence under subsections (1), (2) or (3).

Subsection 42DL(5) has the effect that a person would be committing an offence under subsection 42DL(1), (2) or (3) if a person advertises, or causes the advertising, by any means (publish, broadcast or whatever means), of therapeutic goods, and the advertisement contains a prohibited representation (whether in express terms or by necessary implication) about therapeutic goods, and no permission under subsection 42DK(2) is in force in relation to that representation, or a permission under subsection 42DK(2) is in force in relation to that representation but the use of the prohibited representation is not in accordance with the permission or a condition of that permission.

Subsection 42DL(6) has the effect that a person would be committing an offence if the person advertises, or causes the advertising, by any means, of therapeutic goods and does not contain a required representation about the goods. The required representations are required representations about therapeutic goods of a kind specified in the regulations (refer to subsection 42DJ(2)).

Subsection 42DL(7) provides for an offence concerning restricted representations in advertisements about therapeutic goods. Approval of the use of the restricted representation can be granted by the Secretary under section 42DF. Permission for the use of specified restricted representations in specified advertisements about specified therapeutic goods can also be made by the Secretary under subsection 42DK(1). Subsection 42DL(7) provides in effect that a person would be committing an offence under subsections 42DL(1), (2), or (3) if

a person advertises, or causes the advertising, by any means, of therapeutic goods, if it contains a restricted representation (whether it is expressed or implied) and either of the following applies:

- neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;
- although an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation, the use of the restricted representation in the advertisement about therapeutic goods is not in accordance with that approval or permission, or any condition of the approval or permission

Subsection 42DL(8) provides that a person commits an offence under this section, if that person advertises or causes the advertising, by any means, of therapeutic goods, if the advertisement contains a reference to the Act, other than a statement of the registration number, listing number or the device number of the goods.

Subsection 42DL(9) provides that a person commits an offence under this section, if that person advertises or causes the advertising, by any means, of therapeutic goods, and the advertisement contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority).

Examples of advertisements contravening this subsection are statements or pictorial representation that the therapeutic goods are “TGA approved” or “FDA approved”. However, the following statements, pictorial representation or design are not contraventions of this subsection:

- a statement of the availability of the goods as a pharmaceutical benefit;
- a statement, pictorial representation or design authorised, or required by a government, or government authority (not including a foreign government or foreign government authority)
- a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

Subsection 42DL(10) implements the government’s policy of not allowing for the advertisement of prescription and other restricted medicines to the general public, unless the substances or medicines containing the substances are listed in Appendix H of the current Poisons Standard. Thus, subsection 42DL(10) has the effect that a person commits an offence if the person advertises, or causes the advertising, by any means, of therapeutic goods, and the advertisement refers to substances, or goods containing substances, included in Schedule 3, 4, or 8 to the current Poisons Standard, and at the same time are not listed in Appendix H of the current Poisons Standard. Subsection 42DL(10) does not apply if the advertisement contains a reference authorised or required by an Australian government or government authority.

Biologicals are prohibited from being advertised to the public. Subsection 42DL(11) implements that prohibition, and provides that a person commits an offence under this section if the person advertises, or causes the advertising, by any means, of therapeutic goods, and the advertisement refers to a biological, other than a reference authorised or required by an Australian government or government authority.

Subsection 42DL(12) specifically prohibits the advertising of specified therapeutic goods that are not entered in the Register, subject to certain exclusions. Subsection 42DL(12) has the effect that a person commits an offence under this section, if the person advertises, or causes the advertising, by any means, of therapeutic goods, and the advertisement refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by an Australian government or government authority. Thus, the advertising of therapeutic goods that are subject to the requirement for registration or listing under Part 3-2, inclusion of a biological in the Register under Part 3-2A, and inclusion of a kind of device in the Register under Part 4-5 of the Act, and are not the subject of an exemption, approval or authority from those requirements will be an offence under subsection 42DL(12) (unless the exclusion applies). Subsection 42DL(12) are also proposed to apply to goods that are currently mentioned in paragraph 42DL(1)(h).

Subsections 42DL(13) and (14) provide for the consequences of continued contravention of any the specified advertising requirements under any of subsections (4) - (12) by a person in relation to a particular advertisement about therapeutic goods. In view of the significant rise in the use of electronic means of advertising therapeutic goods, such as on the internet, advertisements are no longer “time limited” in the way that print or broadcast media advertising is. This is in contrast to publications on the newspapers and magazines where the publication date can be established in reference to the particular date of publication. Despite confirmation or warning of the contravention, some advertisers have continued to leave an advertisements on the internet for continued access by the public. By the time a formal direction from the Secretary is made to the advertiser regarding the contravention (such as withdrawal of the advertisement), and following all statutory requirements, the non-compliant advertisement could have been circulating for many months. Where the advertisement contains false or misleading claims, consumers continue to be misled by these claims and in some cases, harm or injury may result. The continuing offences application provisions provide for a strong incentive to comply from the initial confirmation of contravention from the Secretary and to cease or withdraw that advertisement.

Continuing offences provide a strong incentive for compliance with a continuing obligation (for example to withdraw the advertisement or cease the circulation of the advertisement) following an initial contravention. The continuing offence is clearly expressed so that a person is aware that a continued failure to comply will lead to further offences being committed. Subsections 42DL(13) and (14) are consistent with the continuing offence provisions set out in sections 136 and 213 of the *Broadcasting Services Act 1992*. Section 136

relates to breaches of the requirements under Division 1 of Part 10 of that Act in relation to breaches of licensing provisions. Section 213 provides that if an offence against that Act is a continuing offence, the maximum penalty for each day that the offence continues is 10% of the maximum penalty that could be imposed in respect of the principal offence.

Subsection 42DL(13) makes it clear that a person who contravenes subsection (1) (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

Subsection 42DL(14) provides that the maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence. That is, the maximum penalty for the first day the offence was committed would be those specified in subsections (1), (2) or (3), and the 10% applies for the contravention after that day that the contravention continues to be committed by the same person. It is emphasised that the penalty only applies to the pecuniary penalty and not the term of imprisonment.

#### Section 42DLA

Item 35 also inserts a new section 42DLA, a tiered offence which replaces the existing subsection 42DL(1)(d). The offences apply where a person does an act or omits to do an act and the act or omission contravenes a section 42DKB notice given to that person by the Secretary in relation to therapeutic goods. A section 42DKB notice would generally be issued to prevent advertising or the continuation of advertising where the representation in the advertisement about therapeutic goods is false or misleading. Consumers may suffer harm or injury when using therapeutic goods when advertised in these circumstances. Timely removal of the advertisement is required for the protection of public health.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, the contravention of which may result or would result in harm or injury to a person, the new section 42DLA introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the goods has resulted in, or will result in, harm or injury to any person, or the use of the goods, if the goods were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 42DLA(1));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 42DLA(2)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 42DLA(3) and (4)).

#### Section 42DLB

Item 35 also inserts civil penalty provisions, subsections 42DLB(1) to (9) corresponding to the tiered offence provision provided for under section 42DL.

Contravention of subsection 42DLB(1) attracts a maximum pecuniary penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

#### Section 42DLC

Item 35 also inserts a new civil penalty provision section 42DLC in relation to non-compliance with a notice issued to a person under section 42DKB. The new section 42DLC attracts a maximum pecuniary penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

#### Section 42DM

Item 35 also replaces section 42DM with a new section 42DM tiered offence regime and a corresponding civil penalty (section 42DMA).

References to a person committing an offence if the person ‘publishes or broadcasts’ an advertisement about therapeutic goods that does not comply with the Advertising Code have been replaced with references to ‘advertise by any means’. Subsection 42DM(2) provides that this offence is a strict liability offence.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, the contravention of which may result or would result in harm or injury to a person, new section 42DM introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the goods has resulted in, or will result in, harm or injury to any person, or the use of the goods, if the goods were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 42DM(1));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 42DM(2); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 42DM(3) and (4)).

In addition to applying to the person who advertises the therapeutic goods or causes the advertising of the therapeutic goods, new section 42DM applies to persons who contracted other persons, employed other persons or commissioned other persons to advertise therapeutic goods.

Item 35 also adds new subsections 42DM(5) and (6). Subsection 42DM(5) make it clear that a person who contravenes the offence provisions under subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contraventions continues. This provision addresses the situations wherein advertisers despite being put on notice through a warning letter, or other notification processes about the contravention continue to advertise the therapeutic goods. This is particularly the case in advertisement through the internet.

Subsection 42DM(6) provides that the maximum penalty for each day that an offence against subsections (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence. That is, the maximum penalty for the first day the offence was committed would be those specified in subsections (1), (2) or (3), and the 10% applies after that day.

The justification for the application of continuing offence provisions discussed under subsections 42DL(13) and (14) also apply to subsections 42DM(5) and (6).

#### Section 42DMA

Item 35 also adds a new section 42DMA which is the corresponding civil penalty provision to the offence provisions under section 42DM. Contravention of section 42DMA attracts a maximum pecuniary penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

#### **Item 36**

The current section 42DO provides that generic information (noting that generic information is not an advertisement about therapeutic goods) to which Division 4 applies must also comply with the principles of the Advertising Code specified in the regulations made for the purposes of section 42DO as if those principles applied to generic information in the same way as they apply to advertisements.

Item 36 omits reference to principles of the Advertising Code in section 42DO, and makes it clear that it is provisions of the Code that are prescribed in the Regulations for the purposes of this section are the applicable provisions in relation to generic information in the same way as they apply to advertisements about therapeutic goods.

#### **Item 37**

#### Section 42DP

Current section 42DP provides for an offence in relation to the publication or broadcast of generic information about therapeutic goods and the publication or broadcast does not comply with the principles contained in the part of the Advertising Code that are specified in the Regulations.



Item 37 replaces the current section 42DP with a new two-tiered offence. That is a general offence under subsection 42DP(1) applying to the dissemination, by any means, of generic information about therapeutic goods to the public or a section of the public, and the dissemination of that generic information does not comply with the provisions of the Advertising Code that are prescribed by regulations for the purposes of section 42DO. This offence attracts a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both.

A corresponding strict liability offence to the offence is provided for under subsections 42DP(2) and (3), and attracts a maximum penalty of 100 penalty units.

The changes to section 42DP reflect the proposed changes to section 42DO that no longer refers to principles of the Advertising Code, and now refers to dissemination of generic information by any means. References to “disseminate” instead of “publish or broadcast” are consistent with the definitional change made under Item 1.

The harm relating to the advertising of therapeutic goods to the public primarily arises because of the actual use of that advertised good. The act of dissemination of generic information does not, without more, cause harm an aggravated offence in these circumstances would not be appropriate.

#### Section 42DQ

Item 37 also adds a new civil penalty provision section 42DQ which is the corresponding civil penalty provision to the offence provisions set out in section 42DP. Contravention of section 42DQ attracts a maximum pecuniary penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

#### **Item 38**

Item 220 adds a new Division 5, Division 6 and Division 7 in Part 5-1 of the Act.

#### *Division 5 - Secretary may require information or documents*

The new Division 5 contains new sections 42DR, 42DS, 42DT and 42DU.

#### Section 42DR

New subsection 42DR(1) empowers the Secretary, by written notice to a person apparently responsible for advertising therapeutic goods, or causing the advertising of therapeutic goods, to require that person to give to the Secretary specified information, or to produce to the Secretary specific documents, relating to the advertisement. The information or documents could include technical documents supporting claims or representations in the advertisement about therapeutic goods and information or documents relating to the arrangements (contractual or otherwise) regarding the advertising of therapeutic goods.

Subsection 42DR(2) empowers the Secretary, by written notice to a person apparently responsible for disseminating the generic information or for causing the disseminating of, generic information about therapeutic goods to the public or a section of the public, to require the person to give specified information or to produce specified documents, relating to the dissemination of the generic information.

The person required to provide information or produce documents must give the information or document within the period, of not less than 14 days after the day the notice is given, specified in the notice or within such longer period as the Secretary allows, and must be in the form specified in the notice (refer to subsection 42DR(3)).

The form specified in the notice may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission (refer to subsection 42DR(4)).

### Section 42DS

New subsection 42DS(1) provides for an offence where a person is given a notice under subsection 42DR requiring that person to give specified information or produce specified documents within a specified period and in the specified form, and that person fails to comply with the notice. This offence attracts a maximum penalty of 500 penalty units.

Subsection 42DS(2) is the equivalent strict liability offence of subsection 42DS(1) and attracts a maximum penalty of 100 penalty units.

Subsection 42DS(4) provides that a person commits an offence if the person is given a notice under section 42DR and the person gives information or produces a document in compliance with the notice and the information or document provided by the person is false or misleading in a material particular. This offence attracts a maximum term of imprisonment of 12 months or 1,000 penalty units or both. Subsection 42DS(5) is the equivalent strict liability offence of subsection 42DS(4) and attracts a maximum penalty of 100 penalty units.

### Section 42DT

New section 42DT is the corresponding civil penalty provision for non-compliance with the requirements of the notice under section 42DR, and attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

### Section 42DU

New section 42DU (Self-incrimination) abrogates the privilege against self-incrimination in specified circumstances. Thus, a person who has been required by the Secretary to provide information or produce documents under section 42DR is not excused from giving that information or documents on the ground the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

However, for an individual the following cannot be used in criminal proceedings (except for an offence under subsection 42DS(4) or (5)) or in civil proceedings for a civil pecuniary penalty (except for proceedings under section 42Y for a contravention of section 42DT described above);

- the information given or the document produced; and
- giving the information or producing the document; and
- any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document.

This means that the information can be used by the Secretary to make decisions in relation to contraventions of specific requirements under Part 5-1 of the Act, as they relate to advertising or dissemination of generic information, and in making decisions in relation to therapeutic goods which are the subject of the advertisement.

For example, in relation to a particular advertisement, the Secretary may request the giving of information or production of documents to identify the person responsible for the advertising so that a direction can be given under section 42DV or 42DKB. If the right to the privilege against self-incrimination applied, the recipient of the request would legally be allowed to withhold self-incriminating information of the identity of the person who commissioned the advertisement.

#### *Division 6 – Directions about advertisements or generic information*

Item 38 also adds new sections 42DV, 42DW, and 42DX under Division 6.

#### Section 42DV

New section 42DV authorises the Secretary to issue directions about advertisements or generic information.

Subsection 42DV(1) empowers the Secretary, in writing, to direct the person apparently responsible for the advertising of therapeutic goods, or for causing the advertising of therapeutic goods to do one or more of the following:

- cease the advertisement;
- make a retraction;
- make a correction;
- recover any advertisement that is still in circulation; or
- destroy the advertisement or cease making a particular claim or representation made by the advertisement.

However, subsection 42DV(1) requires that the Secretary must be satisfied that there has been a contravention of the Act or the regulations before issuing the direction to the person.

A breach of any provision of the Advertising Code is a ‘contravention of the Act’, because the contravention of the requirements of the Code is an offence and contravention of a civil penalty provision under section 42DM and 42DMA respectively (Item 35 refers).

Subsection 42DV(2) provides a similar power to the Secretary in relation to the dissemination of generic information about therapeutic goods to the public, or a section of the public.

Both of these provisions give the Secretary, on abolition of the Complaints Resolution Panel the powers that the Panel currently has to make orders to a person apparently responsible in relation to an advertisement about therapeutic goods, and generic information about therapeutic goods. As earlier noted, the provisions in the Regulations relating to the Complaints Resolution Panel are proposed to be repealed and similar powers for the Secretary to obtain advertising compliance need to be established.

The direction under subsection 42DV(1) or (2) may be subject to conditions specified in the direction. The condition may include the giving of evidence to the Secretary that the required actions have been carried out, where the correction or retraction should be published, broadcast or disseminated and for how long, when and how particular advertisements or particular claims or representations that were the subject of the direction can be advertised or disseminated.

Subsection 42DV(6) mandates that as soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department’s website.

### Section 42DW

Section 42DW provides a tiered offence provision in relation to the contravention of a direction under section 42DV.

Similar to existing tiered offences in relation to contravention of other significant regulatory requirements under the Act, contravention of which may result or would result in harm or injury to a person, new section 42DW introduces a new tiered offence consisting of:

- a high level offence that consists of the prohibited conduct, an aggravated element (the use of the goods has resulted in, or will result in, harm or injury to any person, or the use of the goods, if the goods were used, would result or likely result, or be likely to result, in harm or injury to a person) and a nexus element linking the harm or injury as a result of the contravention. The high level offence attracts a higher maximum penalty and terms of imprisonment (imprisonment for 5 years or 4,000 penalty units or both) (refer to new subsection 42DW(1));
- an ordinary offence attracting a maximum penalty of imprisonment for 12 months or 1,000 penalty units or both (refer to new subsection 42DW(2)); and
- a strict liability offence within the meaning of the Criminal Code Act, attracting a maximum penalty of 100 penalty units (refer to new subsections 42DW(3) and (4)).

## Section 42DX

The corresponding civil penalty provision for the offences under section 42DW is provided for under section 42DX. The contravention of section 42DX attracts a maximum pecuniary penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

*Division 7- Public warning notices.*

Item 38 also adds new section 42DY under Division 7.

## Section 42DY

New subsection 42DY(1) under Division 7 of Part 5-1 empowers the Secretary to issue written public warning notices containing a warning about therapeutic goods if the Secretary reasonably suspects that there has been a contravention of the Act or the Regulations in relation to the advertising of therapeutic goods or the dissemination of generic information about therapeutic goods to the public or a section of the public and the Secretary is satisfied that it is in the public interest to issue the notice. As mentioned in relation to section 42DV, although the Advertising Code is not referred to in this provision, any breaches of a requirement or provision under the Advertising Code is covered within the scope of the term 'contravention of the Act'.

Subsection 42DY(2) provides that without limiting subsection (1), if the Secretary gives a person a notice (substantiation notice) under subsection 42DR(1) or (2) and that person fails to comply with the substantiation notice and the Secretary is satisfied that it is in the public interest to issue a notice under this subsection, the Secretary can then issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related. The written notice would be made on the Departmental website.

## **Items 39 to 42**

Items 39 to 42 insert new provisions in the Table provided under section 53A.

Section 53A provides for the alternative verdicts for various offences. Section 53A provides that if a jury acquits a person for an offence against a provision listed in column 2 of an item in the table, but is satisfied beyond reasonable doubt that the person is guilty of the offence listed in column 3 of that item (generally the common offence with no aggravated element), the jury may convict the person of the offence listed in column 3 of that item.

Items 39 to 42 inserts new subsections 22(2) and (3), 32BJ(2A) and (2B), 41ML(1) and (2), 42DL(1) and (2), 42DLA(1) and (2), 42DM(1) and (2), and 42DW(1) and (2) in the table following section 53A. The inclusion of these provisions means that the alternative verdict provisions apply to the aggravated offence substituting the general offence specified in the those subsections.

## **Items 43 to 46**

Items 43 to 46 insert new subsections 22(2) or (7AB), 32BJ(2A), 41ML(1), 42DL(1), 42DLA(1), 42DM(1) and 42DW(1) in the table under section 54BA which have the effect that executive officers may be personally liable under those corporate offences.

## **Item 47**

Item 47 adds subsections 42DV(1) or (2) in the list of reviewable decisions under section 60 of the Act. Inclusion in the list makes these decisions available for an internal review under section 60 of the Act and by the Administrative Appeals Tribunal, subject to the requirements set out under this section.

## **Item 48**

Subitem 1 of Item 48 provides that the offence provisions set out in new subsections 21B(4), and 22(2),(3) and (5) (advertising a therapeutic good that is entered in the Register but the indication of the good in the advertisement is not consistent with the indication accepted with the inclusion of the good in the Register), apply in relation to advertisements first occurring on or after the commencement of this item. Advertisements that were made before the commencement date of this Part, and continue to be advertised on or after the commencement date would be prosecuted under the previous provisions, noting that no civil penalty provision applies to the specified contravention on or before the commencement date.

Subitem (2) makes it clear that despite the amendments made by this Part, paragraph 30(1)(f) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of Item 48, continues to apply on or after that commencement in relation to a direction or requirement referred to in that paragraph that was given or made before that commencement.

Thus, any directions made by the Complaints Resolution Panel (a committee established under regulation 42R of the *Therapeutic Goods Regulations 1990*) in relation to an advertisement continue to apply, despite the amendments made to subsection 30(1). Regulation 9 of the *Therapeutic Goods Regulations 1990* will also continue to apply.

Subitem (3) provides that new paragraph 30(1)(fb) of the *Therapeutic Goods Act 1989* applies in relation to a breach occurring on or after the commencement of Item 48.

Subitem (4) provides that new subsection 30(1AA) of the *Therapeutic Goods Act 1989*, applies in relation to a breach occurring on or after the commencement of Item 48. Note, however, that subsection 30(1AA) is an exemption applying to export only medicines.

Subitem (5) provides that despite the amendments made by this Part, paragraph 30(1A)(c) and subsection 30(1B) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of Item 48, continue to apply on and after that commencement in relation to a breach occurring before the commencement date.

## **Item 49**

Subitem (1) of Item 49 provides that the offence provisions set out in new subsections 32BJ(2A), (2B) and (3A) and subsection 32BL (advertising a biological that is entered in the Register but the indication of the biological in the advertisement is not consistent with the indication accepted with the inclusion of the biological in the Register), apply in relation to advertisements first occurring on or after the commencement of this item. Advertisements that were made before the commencement date of this Part, and continue to be advertised on or after the commencement date would be prosecuted under the previous provisions, noting that no civil penalty provision applies to the specified contravention on or before the commencement date.

Subitem (2) makes it clear that despite the amendments made by this Part, paragraph 32GA(1)(i) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of Item 49, continues to apply on or after that commencement in relation to a direction or requirement referred to in that paragraph that was given or made before that commencement. Thus, any directions made by the Complaints Resolution Panel (a committee established under regulation 42R of the *Therapeutic Goods Regulations 1990*) in relation to an advertisement continue to apply, despite the amendments made to subsection 32GA(1).

Regulation 9 of the *Therapeutic Goods Regulations 1990* will also continue to apply.

Subitem (3) provides that despite the amendments made by this Part, paragraph 32GA(1)(j) (relating to a breach of the Advertising Code or any requirement relating to advertising applicable under Part 5-1) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this Item, continues to apply on or after that commencement in relation to a breach before that commencement.

Subitem (4) provides that new paragraph 32GA(1)(k) of the *Therapeutic Goods Act 1989*, applies in relation to a breach occurring on or after the commencement of Item 49.

## **Item 50**

Subitem 1 makes it clear that despite the amendments made by this Part, paragraph 41GL(g) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of Item 50, continues to apply on or after that commencement in relation to a direction or requirement referred to in that paragraph that was given or made before that commencement. Thus, any directions made by the Complaints Resolution Panel (a committee established under regulation 42R of the *Therapeutic Goods Regulations 1990*) in relation to an advertisement continue to apply, despite the amendments made to subsection 41GL. Regulation 9 of the *Therapeutic Goods Regulations 1990* will also continue to apply.

Subitems 2 and 3 provide that the amendment of paragraphs 41GL(h) and 41GN(1)(k) of the *Therapeutic Goods Act 1989* made by this Part apply in relation to a breach or contravention occurring on or after the commencement of this item.

Subitem 4 provides that section 41ML as substituted by this Part and the corresponding civil penalty provision section 41MLB as inserted by this Part apply in relation to advertisements first occurring on or after the commencement of Item 50. Thus, if the internet advertisement commenced prior to the commencement of Item 50 and continues after the commencement date of this Item, the previous section 41ML offence applies, and no civil penalty contravention applies to the making of the advertisement.

## **Item 51**

Subitem (1) provides that new subsection 42DKB(1) substituted by this Part applies in relation to advertisements first mentioned in this subsection that occurs on or after the commencement of this item and to an advertisement that occurs in period of 60 days prior to the commencement where no notice had been given under the old subsection 42DKB(1).

Subitem (2) provides that the repeal and substitution of subsection 42DKB(1) of the *Therapeutic Goods Act 1989* made by this Part does not affect the validity of a notice given under that subsection before the commencement of Item 51.

Subitem (3) provides that new subsection 42DKB(3) as added by this Part only applies in relation to notices given on or after the commencement of this Item.

Subitem (4) provides that the new tiered offence provision section 42DL substituted by this Part applies in relation to advertisements first occurring or made available to the public on or after the commencement of this Item.

Subitem (5) makes it clear that the repealed section 42DL as in force immediately before the commencement of this Item, continues to apply on or after the commencement of this Item in relation to advertisements published or broadcast before that commencement, and also to an advertisement published or broadcast on or after that commencement, where a notice was given under section 42DKB of the Act before that commencement.

Subitem (6) provides that new sections 42DLA and 42DLC apply in relation to section 42DKB notices given on or after the commencement of this Item.

Subitem (7) provides that new sections 42DLB, 42DM and 42DMA apply to advertisements occurring on or after the commencement of this Item.

Subitem (8) provides that section 42DM in force immediately before the commencement of this Item continues to apply in relation to publications or broadcasts of an advertisement occurring before the commencement of this Item.

Subitem (9) provides that new sections 42DP and 42DQ of the *Therapeutic Goods Act 1989* apply in relation to the dissemination of generic information about therapeutic goods occurring or made available to the public on or after the commencement of this Item.



Subitem (10) makes it clear that the repealed section 42DP of the *Therapeutic Goods Act 1989*, as in force, immediately before the commencement of this Item continues to apply on or after that commencement in relation to publications or broadcasts occurring before that commencement.

Subitem (11) provides that new Divisions 5, 6 and 7 of Part 5-1 of the *Therapeutic Goods Act 1989*, as added by this Part, apply in relation to the following:

- advertisements occurring before, on, or after the commencement of this Item, and
- the dissemination of generic information about therapeutic goods, occurring before, on or after the commencement of this Item.

This subitem is important to empower the Secretary to request information and documents to advertisers and persons apparently responsible for the advertisement regarding breaches, advertisements or contravention occurring before the commencement of this Item and where the requirements and provisions were in force before commencement and continue to apply after the commencement of this Item.

## **Schedule 6 – Advertising**

### **Part 2 – Removal of requirement for advertisements to be approved**

Under the current (prior to the amendments effected by the Bill) regulatory framework for therapeutic goods advertising, there are inconsistencies in the types of therapeutic goods and media that require advertising pre-approval. For example, medical device advertisements are not subject to pre-approval. However, complementary and certain OTC medicine advertisements for television, radio, magazines and newspapers require pre-approval, while internet advertisements of these goods do not. Further, advertisers wishing to advertise complementary and certain OTC medicines in a multi-media campaign require approval from two separate bodies. Advertising pre-approval, however, does not protect advertisers from being found non-compliant with the advertising requirements. The involvement of multiple parties in pre-approvals and complaints handling has resulted in inconsistent decisions about advertisements. These issues could result in increased regulatory burden for industry and limit the effectiveness of advertising compliance which has been detrimental for consumers.

The pre-approval mechanism will be removed but other consumer protections will be implemented prior to this occurring, such as an improved complaints handling system and enhanced sanctions and penalties.

### **Consequential amendments**

*Broadcasting Services Act 1992*

#### **Items 52 to 58**

Items 52 to 58 amend the *Broadcasting Services Act 1992* to reflect the repeal of the advertising pre-approval requirements under the *Therapeutic Goods Act 1989*.

Item 52 repeals clause 6 of Schedule 2. Clause 6 of Schedule 2 to the *Broadcasting Services Act 1992* provides that a broadcaster is prohibited from broadcasting an advertisement relating to therapeutic goods that is required to be approved under the *Therapeutic Goods Act 1989*, unless the text of the advertisement has been so approved. As pre-approval will no longer be a requirement for these advertisements, clause 6 is to be repealed.

Items 53 to 58 omits all reference to clause 6 of Schedule 2 as a consequence of Item 52 above

*Therapeutic Goods Act 1989*

#### **Item 59**

Item 59 repeals specified definitions that are no longer required in view of the repeal of Division 2 of Part 5-1 of the Act which relates to pre-approval of specified advertisements. The definitions of generic information, required information and restricted representation are not repealed as they are still referred to in existing and new provisions.

#### **Item 60**

Item 60 repeals Division 2 of Part 5-1 which is about pre-approval of therapeutic goods advertisements.

#### **Item 61**

Item 61 repeals section 42DA and substitutes it with new simplified outline of Division 3 of Part 5-1 of the Act.

The simplified outline now refers to the three kinds of representations in advertisements about therapeutic goods covered by this Division: restricted representations, required representations and prohibited representations. It also refers to offences and civil penalty provisions in Division 3A.

#### **Item 62**

Item 62 repeals paragraph 42DF(4)(a) as a consequence of the proposed repeal of the provisions in the regulations in relation to the Therapeutic Goods Advertising Code Council.

#### **Item 63**

Item 63 repeals the heading of Division 3A of Part 5-1 and substitute it with a new heading:

“Division 3A- Advertising Offences and Civil Penalties”.

#### **Item 64**

Item 64 repeals section 42DKA. In view of the repeal of the pre-approval of advertisements provisions, there is no longer a need to differentiate advertisements about therapeutic goods that require pre-approval and those that do not require pre-approval.

## **Item 65**

Subitem(1) provides that despite the amendments made by this Part, Divisions 1 and 2 of Part 5-1 under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* that relate to pre-approval of specified advertisements in relation to specified therapeutic goods, and as in force immediately before the commencement of this Item, continue to apply on or after that commencement to advertisements published or broadcast before that commencement.

Subitem (2) provides that despite the amendments made by this Part repealing clauses 6,7, 8, 9 and 11 of Schedule 2 to the *Broadcasting Services Act 1992*, clauses 6, 7, 8, 9 and 11 as in force immediately before the commencement of this Item, continue to apply on and after that commencement in relation to advertisements relating to therapeutic goods that were broadcast before that commencement.

Subitem (3) provides that despite the amendments made by this Part, clause 24 of Schedule 6 to the *Broadcasting Services Act 1992*, as in force, immediately before the commencement of this Item continues to apply on or after that commencement in relation to advertisements in relating to therapeutic goods that were provided on datacasting service before that commencement.

## **SCHEDULE 7 — Enforcement**

### ***Therapeutic Goods Act 1989***

Schedule 7 amends the *Therapeutic Goods Act 1989* (the Act) to provide for a more effective approach to compliance and enforcement by tailoring regulatory action to the severity of the compliance breach, consistent with whole of government policy.

The amendments:

- revise the tiered offence structure first inserted into the Act in 2006 by strengthening the existing aggravating elements in fault-based criminal offences in the Act to include likelihood of harm or injury to any person;
- standardise most strict liability offences in the Act by reducing penalties from 2,000 to 100 penalty units and removing the ‘harm’ element from strict liability offences throughout the Act;
- complement some stand-alone fault-based offences in the Act with corresponding strict liability offences;
- complement, clarify and enhance compliance monitoring and investigations powers with provisions based on Parts 2 and 3 of the *Regulatory Powers (Standard Provisions) Act 2014* (RPSPA);
- replace the current infringement notice scheme with provisions based on Part 5 of the RPSPA to create a viable alternative scheme to formal litigation for strict liability offences and for contraventions of civil penalty provisions;
- introduce injunctions to enforce regulatory provisions by restraining a person from contravening a provision or compelling a person to comply with a provision in the Act. The injunction provisions are based on Part 7 of the RPSPA.

The measures relating to monitoring and investigation, infringement notices and injunctions involve adopting provisions based on Parts 2 and 3 of the RPSPA, rather than triggering the provisions in the RPSPA itself. As the Act has been applied as a law of each of the States, it must be capable of operating within each State jurisdiction as well as Commonwealth jurisdiction. As the State laws applying the Act do not also apply the RPSPA, mirroring the relevant provisions of the RPSPA in the Act ensures that those provisions will be applied as part of the applied Act in each State jurisdiction.

Schedule 7 makes a number of similar amendments to multiple provisions throughout the Act. For ease of reading, general descriptions of the nature of each kind of change have been included. The amending items that involve changes of that kind are identified in tables in the Annex to this Part.

### ***Tiered offence regime***

The Act contains a large number of three-tiered sets of offences. Each of these sets of offences includes:

- a fault-based offence with an aggravating element (for conduct that results in, or will result in, harm or injury), generally attracting a maximum penalty of 4,000 penalty units and/or 5 years imprisonment;
- a strict liability offence with an aggravating element (conduct likely to result in harm or injury), generally attracting a maximum penalty of 2,000 penalty units with no term of imprisonment;
- a fault-based offence (with no aggravating element), generally attracting a maximum penalty of 1,000 penalty units and/or 12 months imprisonment.

The purpose of an appropriately tiered regime of criminal offences is intended to tailor penalties to criminal conduct so that more serious offences resulting in or likely to cause harm or injury will attract appropriate sanctions. The penalties for the offences with aggravating elements (“aggravated offences”) are significantly higher than the offences without the aggravating element, to reflect the fact that breaches of these provisions have resulted in, or will or are likely to result in, a serious and direct threat to public health and safety.

To achieve this purpose, the Bill modifies the current tiered offences regime throughout the Act, with sanctions that match the degree of seriousness of the consequences of conduct that currently constitutes an offence. The new three tiered offences regime structure will consist of the following three alternative offences:

- a fault-based offence with an aggravating element (for conduct that results in, or will result in, harm or injury) modified to include cases where the conduct is likely to result in harm or injury (taken from the current strict liability offences), generally attracting a maximum penalty of 4,000 penalty units and/or 5 years imprisonment (the same as the current penalty);
- the existing fault-based offence (with no aggravating element), generally attracting a maximum penalty of 1,000 penalty units and/or 12 months imprisonment (the same as the current penalty);
- a strict liability offence modified to remove the current aggravating element (conduct likely to result in harm or injury), with the maximum penalty reduced from 2,000 penalty units to 100 penalty units with no term of imprisonment. The modified strict liability offences will now form the bottom tier of each three-tiered offence regime.

The example of subsection 9G(1), (2) and (4) as presently included in the Act and as amended by the Bill serves to illustrate the realignment to the existing provision to provide for the new ‘tiered’ scheme.

### ***Current section 9G***

For example, subsections 9G(1), (2) and (4) currently provide that a person commits an offence if:

- the person makes a statement; and

- the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and
- the statement is false or misleading in a material particular.

Currently, a person will only have committed an offence under subsection 9G(1) if an additional element (the aggravating element) is present that is either:

- the use of the goods has resulted in, or will result in, harm or injury to any person; or
- the use of the goods, if the goods were used, would result in harm or injury to any person.

The maximum penalty for this offence is 5 years imprisonment, 4,000 penalty units or both.

Under subsection 9G(2), an additional element requires that the use of the goods, if the goods were used, would be likely to result in harm or injury to any person. Strict liability applies to this offence, and the maximum penalty is 2,000 penalty units.

There are no additional elements for an offence against subsection 9G(4). The maximum penalty for this offence is 12 months imprisonment, 1,000 penalty units or both.

### ***New section 9G***

Subsection 9G(1) is amended to include the ‘likely to result in’ element in subsection 9G(1), so that the aggravating element for an offence against that subsection will now be that either:

- the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
- the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person.

With the removal of the aggravating element for an offence against the strict liability offence, the penalty is reduced to 100 penalty units and it is relocated to follow the fault-based offence at subsection 9G(4).

The measures will realign the current tiered offences regime to better reflect regulatory response to harm with a fault-based aggravated offence at the apex, a fault-based offence without harm as the central offence and the new strict liability offence without harm at the base. These measures will fill the current regulatory gap between non coercive measures such as guidance, education and warnings and the coercive actions of formal litigation.

The test for fault-based offences that include a likelihood of harm or injury is an objective test, where the conduct/use of the goods “is likely to result in harm or injury to any person”. Moving the “likely to result in harm or injury” element into a fault-based offence will require that the prosecution prove that the defendant knew that harm or injury was a likely result, or was reckless as to whether harm or injury was a likely result of the defendant’s conduct.

### ***Aggravated fault-based offences***

The current aggravated fault-based offences are the top tier in each three-tiered offence regime. The aggravating elements generally take one of two forms, focussing either on the use of the goods or a relevant act or omission.

The offences that focus on the use of the goods generally apply where:

- the use of the goods has resulted in, or will result in, harm or injury to any person; or
- the use of the goods, if the goods were used, would result in harm or injury to any person.

The offences that focus on a relevant act or omission generally apply where:

- the act or omission has resulted in, or will result in, harm or injury to any person.

As noted above, the amendments modify the aggravating elements to include likelihood of harm or injury to any person. At present, cases where harm or injury is likely, but not certain, are covered by the second tier, strict liability offences.

The amendments do not affect the conduct elements of the offences. They also leave the penalties for the top-tier offences unchanged. Except as noted below, the maximum penalties are 5 years imprisonment or 4,000 penalty units, or both. These penalties remain appropriate, reflecting the culpability of engaging in conduct where harm or injury is a certain or likely result, and the person engaging in the conduct knows, or is reckless as to, that fact.

The amendments to aggravated fault-based offences are outlined in Table 1 in the Annex.

### ***Consequential amendments***

A number of the top tier fault-based offences require a link between the harm or injury involved in the offence and a particular circumstance involved in the commission of the offence, or contain a defence where the harm or injury does not result from a particular circumstance. The Bill amends the provisions setting out these requirements to insert a reference to harm or injury being likely. These amendments are necessary as a consequence of the amendments mentioned above.

The consequential amendments are outlined in Table 2 in the Annex.

### ***Strict liability offences***

As earlier noted, currently, aggravated strict liability offences are the middle tier in the three-tiered offence regime and usually attract a maximum penalty of 2,000 penalty units. Each offence has an aggravating element, which is typically either:

- the use of the therapeutic goods, if the goods were used, would be likely to result in harm or injury to any person, or
- the act or omission is likely to result in harm or injury to any person.

The amendments to all middle tier aggravated strict liability offences do not affect the conduct elements of the offences. The amendments will remove the aggravating elements requiring likelihood of harm or injury to any person. The new strict liability offences will have a significantly reduced maximum penalty of 100 penalty units.

Given the importance of having an effective deterrent to action that could threaten the health and safety of the Australian public, and the importance of ensuring that sponsors and manufacturers have a high level of care in the course of engaging in commercial activities that have a direct impact on public health, the inclusion of strict liability offences in the regulatory scheme is considered to be warranted. The inclusion of a strict liability offence as part of each three-tier offence regime allows enforcement to be tailored to the circumstances of each case. It also enables the enforcement of requirements either by prosecution or by the issuing of an infringement notice.

The 100 penalty unit maximums for the new strict liability offences are considered appropriate. Although they are higher than the usual maximum for strict liability offences, this is justified because of the potential risk to public health arising from the misuse of therapeutic goods. The conduct involved in each of these offences is sufficiently serious that, if the defendant were convicted of an equivalent fault-based offence, a much higher penalty could be imposed, including a significant term of imprisonment.

The effect of these amendments will now make the strict liability offence the bottom tier of the three-tiered offence regimes. The amendments will fill the current regulatory gap by providing options of prosecution of the substantive strict liability offence or the issuance of an infringement notice as an alternative to formal prosecution where appropriate.

The amendments to strict liability offences are outlined in Table 3 in the Annex.

There are also three three-tiered sets of offences, in which the current middle tier is not a strict liability offence (although having the same penalty and aggravating element as other middle-tier offences). The amendments address these offences as follows:

#### **Items 59 and 60**

Items 59 and 60 repeal subsection 21A(11B) (a fault-based offence involving likelihood of harm or injury and a penalty of 2,000 penalty units) and replace it with a strict liability offence at subsection 21A(11D), with no aggravating element and a penalty of 100 penalty units,

#### **Items 153 and 154**

Items 153 and 154 repeal subsection 32CN(6) (a fault-based offence involving likelihood of harm or injury and a penalty of 2,000 penalty units) and replace it with a strict liability



offence at subsection 32CN(8), with no aggravating element and a penalty of 100 penalty units,

### **Items 279 and 280**

Items 279 and 280 repeal subsection 41MO(4B) (a fault-based offence involving likelihood of harm or injury and a penalty of 2,000 penalty units) and replace it with a strict liability offence at subsection 41MO(4D), with no aggravating element and a penalty of 100 penalty units.

These offences relate to the supply of goods by a health practitioner included in a class of practitioners specified in rules under subsection 19B(7A), 32CM(7A) or 41HC(6), where the supply is not in accordance with the rules, not in circumstances specified in the rules, or not in accordance with conditions specified in the rules.

The amendments make the three-tiered offence regimes at subsections 21A(11A) to (11D), 32CN(5) to (8) and 41MO(4A) to (4D) consistent with other three-tiered offence regimes in the Act.

### **Items 143 and 144**

Also, Section 32CJ (which relates to failing to comply with a notice under subsection 32CJ(2) relating to biologicals that are exempt under section 32CB and do not conform to standards etc.) currently contains one fault-based aggravated offence, an aggravated strict liability offence with a maximum penalty of 2,000 penalty units, and another strict liability offence without an aggravating element with a maximum penalty of 60 penalty units. Items 143 and 144 repeal the aggravated strict liability offence, increase the penalty of the existing strict liability offence without an aggravating element from 60 to 100 penalty units, and insert a fault-based offence without an aggravating element at subsection 32CJ(7), forming a three-tier offence regime consistent with other offences in the Act.

### ***Complementary strict liability offences***

The Act contains some stand-alone fault-based offences (with no aggravating elements). The Bill amends the Act, where possible, to complement these stand-alone offences by inserting an offence of strict liability, with no aggravating elements and a maximum penalty of 100 penalty units.

These amendments will fill a current regulatory gap by providing graduated regulatory options of litigation of the substantive fault-based offence or the strict liability offence or the issuance of an infringement notice as an alternative to formal litigation where appropriate.

The amendments inserting strict liability offences to complement existing stand-alone fault-based offences are outlined in Table 4 in the Annex.

### ***Consequential amendments to cross-references***

A number of amendments are made to include cross-references to the new strict liability offence provisions, and to omit references to repealed provisions within existing sections. These amendments ensure that the new offence provisions are treated consistently with existing provisions.

The amendments to cross-references are outlined in Table 5 in the Annex.

### ***Miscellaneous amendments to offences and related provisions in Chapters 1 to 4***

Schedule 7 also makes a number of miscellaneous amendments to items in Chapters 1 to 4 of the Act, for reasons of consistency or as a consequence of the amendments described above.

#### **Item 1**

Item 1 inserts a definition of *Federal Circuit Court* in section 3 of the Act. This term is used in several places in the new Part 5A-4 relating to injunctions (see item 292).

#### **Item 3**

Item 3 amends section 5A of the Act to insert a reference to section 32DO. Section 5A provides that section 15.2 of the *Criminal Code* (extended geographical jurisdiction—category B) applies to certain offences. Section 32DO provides that it is an offence to make a false statement in an application to include a biological in the Register. The equivalent provisions for therapeutic goods registered under Part 3-2 (section 22A) and medical devices (section 41FE) are already provided for by section 5A.

#### **Items 8, 13, 15 and 16**

Items 8, 13, 15 and 16 amend section 14 of the Act to replace the defence applying to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging with appropriate words in the offences at subsections 14(1) and (4) relating to importing non-conforming goods. This is consistent with the offences in that section relating to exporting goods, for which an element of the offence is that “the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia)” (see for example paragraph 14(10)(c)).

This exception is more appropriately dealt with as part of the relevant offence (to be proven by the prosecution) as it is not a matter that will be peculiarly within the knowledge of the defendant. The new strict liability offence at subsection 14(4A) (see item 14 below) also contains this exception as an element of the offence.

#### **Items 54 and 62**

Items 54 and 62 repeal notes relating to alternative verdicts under section 53A. The alternative offences to which these notes refer are in the repealed subsections 22(7A) and (8) (see items 55, 63 and 64 below).

#### **Item 64**

Item 64 repeals subsections 22(7A) and (8) of the Act. These subsections were effectively part of three-tiered offence regimes with subsections 21A(9) and (10), and (12) and (13). They have been replaced with new subsections 21A(9A) and (12A) (see items 55 and 63 below).

#### **Item 80**

Item 80 inserts new subsection 31(5AA) into the Act, providing that new subsection 31(4B) does not apply if the person has a reasonable excuse. Similar provisions are added by items 169 (subsection 32JB(1D)) and 203 (subsection 41JB(3D)). These provisions are consistent with existing provisions at subsections 31(4A), 32JB(1A) and 41JB(3A), which apply to stand-alone offences being complemented by the new strict liability offences to which the new defences apply.

#### **Items 84, 133 and 134**

Items 84, 133 and 134 repeal and replace, respectively, the heading to section 31C, the heading to section 32BG and the heading to subsection 32BG(1). The headings have been revised to reflect the inclusion of multiple offences in sections 31C and 32BG (see items 87 and 135 below).

#### **Items 85, 209 and 212**

Items 85, 209 and 212 insert the subsection number (1) at the start of sections 31C, 41JG and 41JH of the Act. These amendments are a consequence of the addition of new subsections in each of those sections (see items 87, 211 and 213 below).

#### **Items 86 and 210**

Items 86 and 210 repeal notes relating to the privilege against self-incrimination. Similar provisions elsewhere in the Act do not have equivalent notes, and the Act includes clear provisions relating to self-incrimination (see in particular sections 31F and 41JJ).

#### **Items 91, 94, 97 and 99**

Items 91, 94, 97 and 99 repeal and replace notes relating to the evidential burden for exceptions to offences. The new notes include a reference to subsection 13.3(3) of the *Criminal Code*.

### **Items 100, 101 and 102**

Items 100, 101 and 102 amend section 31F of the Act (self-incrimination) to apply that section to notices under section 31 of the Act as well as those under sections 31A, 31AA, 31B and 31BA, and to provide that information, or a document, given under a notice is admissible in evidence in criminal proceedings under, or arising out of, subsection 31(5A), (6) or (7) and in civil proceedings under section 42Y for a contravention of section 31AAA (false or misleading information or documents). This is consistent with other requirements to give information or documents (see in particular sections 32JD and 41JC).

### **Items 117 and 132**

Items 117 and 132 insert a new section 32BBA, and a new subsection 32BF(7), into the Act under which biologicals that are imported or exported illegally may be forfeited to the Crown under section 229 of the *Customs Act 1901* as if they were prohibited imports or prohibited exports under that Act. This provision is consistent with similar provisions for therapeutic goods that are registered or listed under Part 3-2 of the Act, medical devices (subsections 19B(7) and 19D(5), and section 41MI) and counterfeit therapeutic goods (section 42F).

### **Items 138, 154, 159, 163, 167, 173 and 177**

Items 138, 154, 159, 163, 167, 173 and 177 repeal and replace penalties. These amendments reflect that the subsections to which these penalties apply are no longer the final subsection in their respective sections. The amount of each penalty is unchanged.

As well as being consistent with defences to similar existing offences, the inclusion of these defences is appropriate as it reflects the fact that it would be significantly more difficult and costly for the prosecution to in effect prove a negative – i.e. that there was no reasonable excuse for a defendant – as the matters that might comprise a reasonable excuse would in most cases be peculiarly within the knowledge of the defendant.

### **Items 229, 234 and 235**

Items 229, 234 and 235 amend section 41MA of the Act to replace the defence applying to medical devices that do not comply with the essential principles to the extent to which those principles relate to labelling medical devices for supply in Australia with appropriate words in the offences at subsections 41MA(9) and (12) (and the new offence at subsection 41MA(13A)) relating to exporting non-complying medical devices. This is consistent with the offences in that section relating to importing medical devices, for which an element of the

offence is that “the medical device does not comply with the essential principles relating to matters other than the labelling of the device” (see for example paragraph 41MA(1)(b)).

This exception is more appropriately dealt with as part of the relevant offence (to be proven by the prosecution) as it is not a matter that will be peculiarly within the knowledge of the defendant. The new strict liability offence at subsection 14(4A) (see item 14 below) also contains this exception as an element of the offence.

### **Item 236**

Item 236 amends section 41MAA of the Act to limit the application of the civil penalty provision relating to exporting medical devices that do not comply with the essential principles to principles other than the labelling of the device for supply in Australia, consistent with the amendments made to the offences in section 41MA of the Act by items 229, 234 and 235.

### ***Continuing contraventions of civil penalty provisions***

#### **Item 290**

Item 290 inserts section 42YCA which provides for daily penalties for continuing contraventions of civil penalty provisions, based on section 93 of the RPSPA. This section ensures that a civil obligation to do something by a certain deadline continues until it is done, and is not discharged by failing to meet the deadline. The section also provides that a separate contravention of the civil penalty provision is incurred for every day the obligation is not met. This is necessary to ensure that failure to comply with an obligation does not excuse a person from meeting that obligation. Section 4K of the *Crimes Act 1914* contains a similar provision in relation to offences, and applies to offences against the Act.

Continuing contravention provisions will encourage persons to comply with their obligations under the Act, quickly remedy the non-compliance or return to a position of compliance if the person is in breach. Given the high investment costs and potential profits associated with therapeutic goods, strong financial penalties are likely to be one of the most significant methods to deter non-compliance with the Act providing an additional incentive for companies to comply with Act.

### ***Infringement notices***

#### **Item 291**

Item 291 repeals the current Part 5A-2 and replaces that Part with new provisions based on Part 5 of the RPSPA. Infringement notices provide a viable alternative to prosecution for a criminal offence or the commencement of civil penalty proceedings. This enforcement option recognises that a lengthy prosecution process or civil proceedings may not be the optimal

way of dealing with some breaches of regulatory requirements. Infringement notices provide a person with the option of paying a fine rather than being dealt with before the courts in relation to breaches of regulatory requirements.

An infringement notice will set out the particulars of the breach and will give a person the option of either paying the penalty set out in the notice to expiate the offence/breach or to have the matter dealt with by a court.

Infringement notices may be issued in relation to those breaches of the Act where the assessable elements of a breach of the Act are readily identified. These would be either strict liability offences or, civil penalty provisions which could apply, for example, to breaches of standards including advertising standards. A maximum penalty of 12 penalty units for an individual or 60 penalty units for an incorporated body will apply, aligning with the RPSPA and contemporary Government policy.

The new Part 5A-2 consists of the following provisions.

#### **Section 42YJ**

Section 42YJ sets out a simplified outline for Part 5A-2. This section is based on section 98 of the RPSPA and indicates the role of infringement notices.

#### **Section 42YK**

Subsection 42YK(1), which is based on section 103 of the RPSPA, empowers the Secretary to issue an infringement notice where the Secretary has reasonable grounds to believe a person has contravened a provision of this Act or the regulations that is an offence of strict liability, or a civil penalty provision.

Infringement notices provide a simpler and faster remedy to a suspected contravention of a provision than formal civil or criminal proceedings.

An infringement notice must be issued within 12 months of an alleged contravention. An infringement notice issued later than this is invalid and cannot be enforced.

To ensure the reasons for each notice are clear, a separate infringement notice must be issued for each alleged contravention, unless the contravention relates to an action that should have been completed before a particular time and the ongoing failure to complete the action constitutes multiple contraventions (see subsection 4K(2) of the *Crimes Act 1914* for continuing offences and new section 42YCA of the Act (which is inserted by item 290 of this Schedule) for continuing contraventions of civil penalty provisions).

#### **Section 42YKA**

Section 42YKA, which is based on section 104 of the RPSA, specifies a range of matters that must be included in each infringement notice. This includes a statement that if the infringement notice is paid within 28 days of it being issued, this does not constitute an admission of guilt but does preclude any further liability or proceedings related to the alleged contravention (unless the notice is subsequently withdrawn).

Subsection 42YKA(2) limits the amount payable under an infringement notice that relates to a single contravention to the lesser of one-fifth of the penalty that a court could impose in relation to the alleged contravention, and 12 penalty units for an individual or 60 penalty units for a body corporate. This ensures that infringement notices, which do not reflect a court sanction or constitute an admission of guilt, remain a lesser remedy to alleged contraventions of the Bill.

Subsection 42YKA(3) provides an equivalent limit on the amount payable under an infringement notice that relates to multiple contraventions.

### **Section 42YKB**

To ensure that a person who wishes to pay an infringement notice is not prevented from doing so by financial hardship or other difficulties, section 42YKB, which is based on section 105 of the RPSA, allows a person who has received an infringement notice to apply to the Secretary for an extension of time to pay the infringement notice. The Secretary may extend the period more than once.

### **Section 42YKC**

A person who receives an infringement notice may elect to challenge the notice rather than pay it. Section 42YKC, which is based on section 106 of the RPSA, therefore sets out processes for withdrawing infringement notices and provides guidance as to what information the Secretary must and may take into account in considering whether to withdraw an infringement notice.

A person may apply for a notice to be withdrawn even if they have already paid the amount specified in the infringement notice. If the notice is withdrawn the amount paid must be refunded.

### **Section 42YKD**

Section 42YKD, which is based on section 107 of the RPSA, ensures that paying an infringement notice discharges all liability for the alleged contravention, without constituting an admission of fault. This is appropriate for an administrative remedy that may be discharged without legal advice or adjudication by the courts. However, payment does not discharge liability if the notice is subsequently withdrawn and the amount refunded. In this sense, withdrawing a notice acts as if the notice was never issued.

## **Section 42YKE**

Section 42YKE, which is based on section 108 of the RPSA, clarifies that Part 5A-2 of the Act, dealing with infringement notices, does not make infringement notices a mandatory response to a suspected contravention; they remain a discretionary remedy. Part 5A-2 also does not limit the option to take enforcement action in other ways, limit liability in any way unless an infringement notice is paid, and does not limit a court's ability to determine the amount of a penalty if a person is found to have contravened a provision of this Act or the regulations that is an offence of strict liability, or a civil penalty.

## ***Injunctions***

### **Item 292**

Item 292 inserts Part 5A-4 at the end of Chapter 5A providing for injunctions restraining a person from contravening a provision of the Act or compelling a person to comply with a provision of the Act. These provisions are based on the injunction powers set out in Part 7 of the RPSA.

This new regulatory power will allow the Secretary to rapidly address serious non-compliance with regulatory requirements that might lead to poor public health outcomes, such as advertising unapproved therapeutic goods to the public with false claims as to the medicine's relevant indications, such as its capacity to treat serious diseases including cancer.

The new Part 5A-4 consists of the following provisions:

### **Section 42YM**

Section 42YM sets out a simplified outline for Part 5A-4. This section is based on section 116 of the RPSA and indicates the role of injunctions.

### **Section 42YN**

Section 42YN, which is based on section 121 of the RPSA, empowers the Federal Court or Federal Circuit Court to grant injunctions on application by the Secretary. A court can issue injunctions to prevent a person engaging in particular conduct or issue injunctions to compel a person to engage in particular conduct if the court is satisfied an injunction is necessary or desirable to respond to, or prevent, a contravention of an enforceable provision.

### **Section 42YO**

In some cases, an interim injunction may be required to prevent or require certain action while injunction proceedings are carried out. Section 42YO, which is based on section 122 of



the RPSPA, enables the court to grant an interim injunction while it is considering an application for an injunction under section 42YN. A court cannot require the Secretary to give an undertaking as to damages as a condition of the interim injunction. Refusing to give an undertaking in respect of damages is not grounds for refusing to grant an interim injunction.

### **Section 42YP**

Section 42YP, which is based on section 123 of the RPSPA, provides that injunctions can be varied or discharged by the Federal Court or Federal Circuit Court.

### **Section 42YQ**

Section 42YQ, which is based on section 124 of the RPSPA, provides that a court can issue an injunction to prevent conduct or require a person to engage in specified conduct whether or not the specific conduct is occurring, has occurred in the past, or is likely to give rise to an imminent danger of substantial damage to any other person. This ensures a court can prevent or require conduct to uphold the purposes of the Act without having to wait for countervailing conduct to occur.

### **Section 42YR**

Section 42YR, which is based on section 125 of the RPSPA, clarifies that injunction powers under this Part are additional to, not in replacement of, any other powers of the court.

### ***Monitoring and investigation powers***

The Bill makes a number of amendments to Part 6-2 of the Act. As noted earlier, these changes are largely intended to more closely align the monitoring and investigation powers under the Act with the equivalent powers under Parts 2 and 3 of the RPSPA, and with the powers of inspectors under comparable legislation such as the *Narcotic Drugs Act 1967* and the *Gene Technology Act 2000*.

### **Item 293**

Item 293 amends the heading of section 46 of the Act to read *Searches to monitor compliance with Act or regulations* to better reflect the powers conferred by the section. Currently the heading does not refer to the regulations.

### **Item 294**

Item 294 adds a reference to the powers under new section 48BA (see item 300 discussed below) to subsection paragraph 46(1)(b) to clarify that those powers may be exercised when monitoring compliance with the Act or regulations under section 46.

## **Items 295 and 296**

Items 295 and 296 amend section 46A of the Act, which details the powers of *authorised persons* when monitoring compliance with the Act or regulations by persons who have goods included in the Register, and by the holders of certain licences, authorities and approvals under the Act (the regulated community). This section places obligations on such persons or occupiers of such premises. These amendments allow *authorised persons* when monitoring compliance at premises of the regulated community to:

- examine or observe any activity conducted on the premises, and
- take extracts from or make copies of any books, records or documents.

These powers are consistent with powers that may be exercised, with consent or under a warrant, under section 46 and with the general monitoring powers under section 19 in Part 2 of the RPSPA. Their extension to the regulated community (without the need for consent or warrant) is consistent with the extension of other monitoring powers currently extended to the regulated community by section 46, and is necessary to ensure compliance with the Act or regulations.

## **Item 297**

Item 297 adds a reference to the amended powers in section 48C of the Act (see items 301 to 307 discussed below) to the powers mentioned in section 47 of the Act as being available to *authorised persons* when conducting investigations related to offences and civil penalty provisions. This clarifies when the powers under section 48C may be exercised.

## **Item 298**

Item 298 adds the power to examine or observe any activity conducted on the premises to the general powers of *authorised persons* in relation to premises under subsection 48(1) of the Act. The addition of this power is consistent with the general monitoring powers at section 19 in Part 2 of the RPSPA.

## **Item 299**

Item 299 inserts section 48AA into the Act. Section 48AA is consistent with section 59 in Part 3 of the RPSPA, and provides for completion of the execution of a search warrant after a temporary cessation. If an authorised person leaves the premises for not more than one hour, or if there is an emergency situation, for not more than 12 hours, section 48AA provides he or she may return and continue to execute the warrant so long as it is still in force. Periods of absence from premises can be longer if the occupier consents in writing or, in the case of an emergency situation, on application to a magistrate. This section will assist in ensuring compliance with the Act and regulations.

### **Item 300**

Item 300 inserts a new section 48BA into the Act. This section, which is based on the monitoring powers in sections 20 and 21 in Part 2 of the RPSA, confers powers to use electronic equipment for monitoring compliance with the Act or regulations. The new powers in section 48BA relate to *authorised persons* operating electronic equipment to see whether information relevant to determining compliance with the Act or regulations is accessible by doing so. Subsection 48BA(2) provides that if such information is found, the *authorised person* may remove the information in documentary form, or transfer the information to disk, tape or storage device and remove it from the premises. Subsection 48BA(3) places obligations on *authorised persons* to only operate electronic equipment if the operation can be carried out without damage to the equipment. Subsections 48BA(4) to (9) provide that on reasonable grounds, an *authorised person* can seek expert assistance to operate electronic equipment or give notice to the occupier and secure the equipment for up to 24 hours or longer with an extension through application to a magistrate, until the equipment has been operated by an expert.

### **Items 301, 302, 303, 304, 305, 306 and 307**

Items 301, 302, 303, 304, 305, 306 and 307 amend section 48C of the Act to better align that section with the equivalent investigations provisions in sections 50 and 51 in Part 3 of the RPSA. Section 48C sets out powers for *authorised persons* to operate electronic equipment when conducting investigations related to offences and civil penalty provisions, and to secure electronic equipment when it is necessary to obtain expert assistance. These also clarify that section 48C operates in relation to investigations in relation to offences and civil penalty provisions.

### **Item 308**

Item 308 amends section 48D of the Act, as a consequence of the insertion of section 48BA by item 300. Section 48D provides for compensation for damage caused by the operation of electronic equipment by *authorised persons* because insufficient care was taken. This amendment inserts a reference to section 48BA of the Act to ensure that compensation is payable if damage is caused to equipment as a result of it being operated as mentioned in that section, as well as section 48C. The amended section 48D is consistent with section 29 in Part 2 of the RPSA.

### **Item 309**

Item 309 repeals and replaces subsection 48E(2) of the Act, to be consistent with subsection 64(4) in Part 3 of the RPSA. Section 48E requires an *authorised person* to provide copies of things seized as evidential material under a warrant. Subsection 48E(2) sets out circumstances in which that requirement does not apply. Currently, paragraph 48E(2)(a) excludes materials obtained after operating electronic equipment at premises under section

48C, and paragraph 48E(2)(b) excludes things where the possession of the thing could constitute an offence or the contravention of a civil penalty provision. This amendment substitutes a new subsection 48E(2), without an equivalent of paragraph 48E(2)(a) and clarifying that the reference to an offence includes an offence against any law of the Commonwealth.

### **Item 310**

Item 310 inserts section 48FA into the Act. Section 48FA is based on section 63 in Part 3 of the RPSPA and places an obligation on the occupier of premises to which an investigation warrant relates to provide reasonable facilities and assistance to *authorised persons* or persons assisting *authorised persons* during the execution of the warrant. Failure to provide reasonable facilities and assistance in contravention of section 48FA is an offence with a maximum 30 penalty unit pecuniary penalty. This provision aligns the Act with other Commonwealth regulatory schemes.

### **Item 311**

Item 311 amends subparagraph 49(4)(a)(ii) of the Act to include the powers set out in the new section 48BA (see item 300 discussed above) in the list of powers that a monitoring warrant must authorise an authorised person to exercise in relation to premises. This amendment is consistent with paragraph 32(4)(d)(ii) in Part 2 of the RPSPA.

### **Item 312**

Item 312 amends subparagraph 50(4)(b)(ii) to include the powers set out in section 48C in the list of powers that a warrant under that section must authorise an authorised person to exercise in relation to premises. This amendment is consistent with paragraph 70(4)(h)(ii) in Part 3 of the RPSPA.

### **Item 313**

Item 313 repeals and substitutes the heading of section 51A of the Act. The new heading better reflects the purpose of this section and its application under paragraph 2 of Article 3 of the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products (Geneva, 1970)<sup>1</sup>.

## **Consequential amendments of Chapter 7**

### **Items 314 and 315**

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<sup>1</sup> Australian Treaty Series 1993 No. 2

Items 314 and 315 amend the table of alternative verdicts for various offences in section 53A to replace references to subsections 22(7A) and (8) with subsections 21A(9A) and (12A) (see items 55, 63 and 64) and to include a reference to a conviction for an offence against subsection 32CJ(7) (see item 143) as an alternative verdict in a prosecution for an offence against subsection 32CJ(6).

### **Item 316**

Item 316 amends section 54 of the Act so that a court can order forfeiture of therapeutic goods to the Commonwealth if the court makes an order under section 19B of the *Crimes Act 1914* in respect of a person charged with an offence against the Act (discharging the person without proceeding to a conviction despite being satisfied that the charge is proved). Currently, forfeiture is available only on conviction for an offence or on the making of a civil penalty order.

Due to the potential harm that can arise from the misuse of therapeutic goods, if a charge is proved in relation to therapeutic goods it may be appropriate to order forfeiture of those goods even if the court does not proceed to a conviction. This amendment will allow the court to order that the goods be forfeited where it is inappropriate that the goods be returned to the person from whom they were seized. There is judicial authority indicating that, because of the nature of therapeutic goods, the use of section 19B of the *Crimes Act* will seldom be appropriate.<sup>2</sup>

### **Items 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327 and 328**

Items 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327 and 328 amend the table of offences at section 54BA of the Act for which executive officers of a body corporate may be personally liable. The amendments:  
remove strict liability offences that are affected by the removal of aggravating elements and consequent reduction of penalty, and  
insert the offences at subsections 9G(1), 35B(1) and 41MN(5).

The offences at subsections 9G(1), 35B(1) and 41MN(5) are appropriate for the application of personal liability of executive officers, taking into consideration the principles determined by the Council of Australian Governments for the imposition of personal liability for criminal fault, particularly as an executive officer may only commit an offence under section 54B(1) of the Act where the officer knew the offence would be committed, was in a position to influence the corporation's conduct in relation to the commission of the offence and did not take all reasonable steps to avoid the commission of the offence. They are all serious offences, with maximum penalties of 5 years imprisonment or 4,000 penalty units, or both, and an aggravating element involving harm or injury. In these respects they are similar to

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<sup>2</sup> *Regina v On Clinic Australia P/L* [1996] NSWSC 530, Smart J.

other offences for which section 54BA currently provides for executive officers to be personally liable.

### **Application and saving provisions**

#### **Items 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340 and 341**

Items 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340 and 341 make provision for the application of the amendments made by Schedule 7, and saving of things occurring before the commencement of Schedule 7.

Broadly, items 329 to 335 have the effect that the amendments to offences apply in relation to things done on or after commencement. Where the relevant conduct was engaged in before commencement, the offences as set out before commencement continue to apply, but, where the relevant conduct was engaged in on or after commencement, the new and amended offences apply.

For example, if (before commencement) a person imports therapeutic goods for use in humans, and the goods are not registered, listed, exempt, or the subject of an approval or authority (as mentioned in paragraph (19B)(1)(b) of the Act), the person commits an offence against subsection 19B(1) only if the use of the goods has resulted in, or will result in, harm or injury to any person, or the use of the goods, if the goods were used, would result in harm or injury to any person. If the use of the goods, if the goods were used, would merely be likely to result in harm or injury to any person, the person would not commit an offence against subsection 19B(1), but would commit an offence against subsection 19B(2). This remains the case for an import before commencement, even if the person is prosecuted after commencement.

A person prosecuted under subsection 19B(2) in relation to an import occurring before commencement would be liable, on conviction, to a maximum penalty of 2,000 penalty units. A person could be prosecuted under the new strict liability offence in subsection 19B(4A) only in relation to an import, export, manufacture or supply occurring on or after commencement.

Similarly, a person engaging in conduct before commencement that contravenes subsection 20(1B) of the Act (a fault-based offence) could only be prosecuted under that subsection, requiring proof of appropriate mental elements. A person engaging in the same conduct on or after commencement could be prosecuted under either subsection 20(1B) or the new strict liability offence at subsection 20(1BA).

Additionally, as the strict liability offences enable the issue of an infringement notice, an infringement notice can be issued in respect of an alleged offence against a new strict liability provision only if the offence was alleged to have been committed on or after commencement.

Item 336 provides that the provision for continuing contraventions of civil penalty provisions will apply in relation to an act or thing required to be done, only where the time at which the thing must be done occurs, or the period within which the thing must be done ends, on or after commencement.

Item 337 provides that the new infringement notice provisions, based on the RPSPA, apply only in relation to alleged offences, and alleged contraventions of civil penalty provisions, that occur on or after commencement. For alleged offences, and alleged contraventions, occurring before commencement, the provisions set out in Part 5A-2, and the associated provisions of the *Therapeutic Goods Regulations 1990*, before commencement will continue to apply.

Item 338 provides that injunctions under the new Part 5A-4 of the Act will be available only in relation to contraventions occurring, or proposed to occur, on or after commencement.

Subitems 339(1) and (3) have the effect that most of the amendments of Part 6-2 of the Act apply in relation to entries to premises (whether under section 46, 46A or 47) occurring on or after commencement. Subitem 339(4) provides specifically that the repeal and substitution of subsection 48C(2) of the Act (which provides for the seizure of electronic equipment and associated material or documents produced by the operation of electronic equipment) does not affect the validity of anything done under that section before commencement.

Subitems 339(2) and (5) provide that the new sections 48AA (completing execution of warrant after temporary cessation) and 48FA (responsibility to provide facilities and assistance) of the Act apply in relation to warrants issued on or after commencement. Subitem 339(6) provides that the amendment of section 49 of the Act (about the issue of monitoring warrants) applies in relation to applications for warrants made on or after commencement.

Item 340 provides that the amendment of section 54 of the Act (allowing forfeiture of goods to be ordered where an order under section 19B of the *Crimes Act 1914* has been made) applies in relation to a section 19B order made on or after commencement, regardless of when the person in relation to whom the section 19B order is made was charged)

Item 341 provides that the table in section 54BA of the Act (identifying provisions for which executive officers of bodies corporate can be personally liable in relation to offences committed by the body corporate) continues to apply as in force immediately before commencement in relation to offences committed by bodies corporate before commencement.

**Annex: Tables outlining items making similar amendments**

**Table 1—Additional aggravating elements in fault-based offences**

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
4, 5	Subsection 9G(1)	False statements in requests for variation of entries in the Register	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
9, 10	Subsection 14(1)	Importing therapeutic goods that do not comply with standards	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
18, 19	Subsection 14(6)	Supplying therapeutic goods that do not comply with standards	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
24, 25	Subsection 14(10)	Exporting therapeutic goods that do not comply with standards	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
31	Subsection 15(2) <sup>3</sup>	Act or omission breaching a condition of Secretary's consent under section 14 or 14A	<ul style="list-style-type: none"> <li>• the act or omission is likely to result in harm or injury to any person.</li> </ul>
34, 35	Subsection 19B(1)	Importing, exporting, manufacturing or supplying therapeutic goods that are not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>

<sup>3</sup> The maximum penalty for this offence remains 2,000 penalty units.



<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
44, 45	Subsection 21A(1)	False or misleading statement in certification for listing of certain medicines under section 26A or 26BA	<ul style="list-style-type: none"> <li>the use of the medicine is likely to result in harm or injury to any person</li> <li>the use of the medicine, if the medicine were used, would be likely to result in harm or injury to any person</li> </ul>
48	Subsection 21A(5)	Act or omission breaching a condition of registration or listing of therapeutic goods	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>
51, 52	Subsection 21A(9)	Supplying therapeutic goods under an authority (s 19(5)), except in accordance with the authority, conditions or regulations	<ul style="list-style-type: none"> <li>the use of the goods is likely to result in harm or injury to any person</li> <li>the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
56, 57	Subsection 21A(11A)	Supplying therapeutic goods specified in rules (s 19(7A)), except in accordance with rules etc.	<ul style="list-style-type: none"> <li>the use of the goods is likely to result in harm or injury to any person</li> <li>the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
61	Subsection 21A(12)	Using therapeutic goods (other than registered, listed or exempt goods) not in accordance with approval or authority under section 19 or conditions applicable under subsection 19(4A)	<ul style="list-style-type: none"> <li>if the person used the goods in the treatment of that other person—the use of the goods is likely to result in harm or injury to that other person</li> <li>if the person used the goods solely for experimental purposes in humans—the use of the goods is likely to result in harm or injury to any of those humans.</li> </ul>
65, 66	Subsection 22A(1)	False statements in applications for registration	<ul style="list-style-type: none"> <li>the use of the goods is likely to result in harm or injury to any person</li> <li>the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
70	Subsection 30EC(1)	Failure to comply with requirements relating to public notification and recall of therapeutic goods	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
73, 74	Subsection 30F(4B)	Failure to comply with a notice under subsection 30F(2) (relating to goods that are exempt under section 18A and do not conform to standards etc.)	<ul style="list-style-type: none"> <li>· the use of the goods is likely to result in harm or injury to any person</li> <li>· the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
81, 82	Subsection 31(5A)	False or misleading response in purported compliance with a notice under section 31	<ul style="list-style-type: none"> <li>· the use of the therapeutic goods is likely to result in harm or injury to any person</li> <li>· the use of the therapeutic goods, if the therapeutic goods were used, would be likely to result in harm or injury to any person</li> </ul>
103, 104	Subsection 32BA(1)	Importing a biological that is not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>· the use of the biological is likely to result in harm or injury to any person</li> <li>· the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
110, 111	Subsection 32BB(1)	Exporting a biological that is not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>· the use of the biological is likely to result in harm or injury to any person</li> <li>· the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
118, 119	Subsection 32BC(1)	Manufacturing a biological that is not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>· the use of the biological is likely to result in harm or injury to any person</li> <li>· the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
125, 126	Subsection 32BD(1)	Supplying a biological that is not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>· the use of the biological is likely to result in harm or injury to any person</li> <li>· the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
136	Subsection 32BI(1)	Using biologicals not in the Register and not subject to exemption or approvals	<ul style="list-style-type: none"> <li>if the person used the biological in the treatment of that other person—the use of the biological is likely to result in harm or injury to that other person</li> <li>if the person used the biological solely for experimental purposes in humans—the use of the biological is likely to result in harm or injury to any of those humans.</li> </ul>
140, 141	Subsection 32CJ(6)	Failure to comply with a notice under subsection 32CJ(2) (relating to biologicals that are exempt under section 32CB and do not conform to standards etc.)	<ul style="list-style-type: none"> <li>the use of the biological is likely to result in harm or injury to any person</li> <li>the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
145, 146	Subsection 32CN(1)	Supplying a biological under an authority (s 32CM(1)), except in accordance with the authority, conditions or regulations	<ul style="list-style-type: none"> <li>the use of the biological is likely to result in harm or injury to any person</li> <li>the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
150, 151	Subsection 32CN(5)	Supplying a biological specified in rules (s 32CM(7A)), except in accordance with rules etc.	<ul style="list-style-type: none"> <li>the use of the biological is likely to result in harm or injury to any person</li> <li>the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
156, 157	Subsection 32DO(1)	False statements in applications for including biologicals in the Register	<ul style="list-style-type: none"> <li>the use of the biological is likely to result in harm or injury to any person</li> <li>the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
161	Subsection 32EF(1)	Act or omission in breach of conditions of including a biological in the Register	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>
165	Subsection 32HC(1)	Failure to comply with requirements relating to public notification and recall of biologicals	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
170, 171	Subsection 32JB(2)	False or misleading information or documents in purported compliance with a notice under section 32JA	<ul style="list-style-type: none"> <li>the use of the biological is likely to result in harm or injury to any person</li> <li>the use of the biological, if the biological were used, would be likely to result in harm or injury to any person</li> </ul>
180, 181	Subsection 35(1)	Manufacturing goods unless the goods or person is exempt or a manufacturing licence is in force	<ul style="list-style-type: none"> <li>the use of the goods is likely to result in harm or injury to any person</li> <li>the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
185, 186	Subsection 35(5)	Manufacturing goods that are exempt under section 18A or 32CB while not holding a manufacturing licence	<ul style="list-style-type: none"> <li>the use of the goods is likely to result in harm or injury to any person</li> <li>the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>
190	Subsection 35B(1)	Act or omission in breach of conditions of manufacturing licence by licence holder	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>
193, 194	Subsection 41EI(1)	False statement in connection with an application for a conformity assessment certificate	<ul style="list-style-type: none"> <li>the use of the kind of medical device is likely to result in harm or injury to any person</li> <li>the use of the kind of medical device, if the kind of medical device were used, would be likely to result in harm or injury to any person</li> </ul>
198, 199	Subsection 41FE(1)	False statement in connection with an application to include a medical device in the Register or a certification under section 41FD	<ul style="list-style-type: none"> <li>the use of the kind of medical device is likely to result in harm or injury to any person</li> <li>the use of the kind of medical device, if the kind of medical device were used, would be likely to result in harm or injury to any person</li> </ul>
204, 205	Subsection 41JB(4)	False or misleading information in purported compliance with a notice under section 41JA	<ul style="list-style-type: none"> <li>the use of the kind of medical device is likely to result in harm or injury to any person</li> <li>the use of the kind of medical device, if the kind of medical device were used, would be likely to result in harm or injury to any person</li> </ul>

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
216	Subsection 41KC(1)	Act or omission breaching requirements imposed under section 41KA public notification and recovery	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person.</li> </ul>
219, 220	Subsection 41MA(1)	Importing a medical device that does not comply with essential principles without consent of the Secretary	<ul style="list-style-type: none"> <li>the use of the device is likely to result in harm or injury to any person</li> <li>the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
224, 225	Subsection 41MA(5)	Supplying a medical device that does not comply with essential principles without consent of the Secretary	<ul style="list-style-type: none"> <li>the use of the device is likely to result in harm or injury to any person</li> <li>the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
230, 231	Subsection 41MA(9)	Exporting medical devices that does not comply with essential principles without consent of the Secretary	<ul style="list-style-type: none"> <li>the use of the device is likely to result in harm or injury to any person</li> <li>the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
237	Subsection 41MC(2) <sup>4</sup>	Act or omission in breach of consent by Secretary relating to device essential principles	<ul style="list-style-type: none"> <li>the act or omission is likely to result in harm or injury to any person</li> </ul>
241, 242	Subsection 41ME(1)	Supply of medical device by manufacturer without applying conformity assessment procedures	<ul style="list-style-type: none"> <li>the use of the device is likely to result in harm or injury to any person</li> <li>the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
246, 247	Subsection 41ME(5)	Export of medical device by manufacturer without applying conformity assessment procedures	<ul style="list-style-type: none"> <li>the use of the device is likely to result in harm or injury to any person</li> <li>the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>

<sup>4</sup> The maximum penalty for this offence remains 2,000 penalty units.

<b>Item(s)</b>	<b>Provision</b>	<b>Nature of offence</b>	<b>Additional aggravating elements</b>
251, 252	Subsection 41MF(1)	Supplying a medical device without applying conformity assessment procedures	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
254, 255	Subsection 41MF(3)	Exporting a medical device without applying conformity assessment procedures	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
257, 258	Subsection 41MI(1)	Importing, exporting, manufacturing or supplying a medical device that is not in the Register and not covered by an exemption, approval or authority	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
265	Subsection 41MN(1)	Act or omission breaching condition of inclusion of a medical device in the Register	<ul style="list-style-type: none"> <li>· the act or omission is likely to result in harm or injury to any person.</li> </ul>
268	Subsection 41MN(5)	Act or omission breaching a condition of a conformity assessment certificate	<ul style="list-style-type: none"> <li>· the act or omission is likely to result in harm or injury to any person.</li> </ul>
271, 272	Subsection 41MO(1)	Supplying a medical device under an authority (s 41HC(1)), except in accordance with authority, conditions or regulations	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
276, 277	Subsection 41MO(4A)	Supplying a medical device specified in rules (s 41HC(6)), except in accordance with rules etc.	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>
281, 282	Subsection 41MO(5)	Using a medical device under an approval, except in accordance with the approval	<ul style="list-style-type: none"> <li>· the use of the device is likely to result in harm or injury to any person</li> <li>· the use of the device, if the device were used, would be likely to result in harm or injury to any person</li> </ul>

Item(s)	Provision	Nature of offence	Additional aggravating elements
285, 286	Subsection 42V(6)	0. Failure to comply with recovery of goods subject to actual or potential product tampering	<ul style="list-style-type: none"> <li>• the use of the goods is likely to result in harm or injury to any person</li> <li>• the use of the goods, if the goods were used, would be likely to result in harm or injury to any person</li> </ul>

**Table 2—Consequential amendments relating to fault-based offences**

Item(s)	Provision	Nature of linkage	Additional aggravating elements
11	Paragraph 14(1)(e)	the goods do not conform with the standard	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
20	Paragraph 14(6)(e)	the goods do not conform with the standard.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
26	Paragraph 14(10)(e)	the goods do not conform with the standard.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
39, 40	Subsection 19B(6) (defence)	<ul style="list-style-type: none"> <li>(i) the quality, safety or efficacy of the goods; or</li> <li>(ii) a matter relating to the labelling or packaging of the goods; or</li> <li>(iii) the improper use of the goods</li> </ul>	<ul style="list-style-type: none"> <li>• is not likely to directly result</li> <li>• would not be likely to directly result</li> </ul>
53	Paragraph 21A(9)(e)	<ul style="list-style-type: none"> <li>(i) the supply is not in accordance with the authority; or</li> <li>(ii) the supply is not in accordance with the conditions to which the authority is subject; or</li> <li>(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7)</li> </ul>	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>

Item(s)	Provision	Nature of linkage	Additional aggravating elements
58	Paragraph 21A(11A)(f)	(i) the supply is not in accordance with those rules; or (ii) the supply is not in the circumstances specified in those rules; or (iii) the supply is not in accordance with the conditions specified in those rules	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
75	Subparagraph 30F(4B)(e)	the person failed to comply with that requirement.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
108, 109	Subsection 32BA(6) (defence)	(i) the quality, safety or efficacy of the biological; or (ii) a matter relating to the labelling or packaging of the biological; or (iii) the improper use of the biological	<ul style="list-style-type: none"> <li>• is not likely to directly result</li> <li>• would not be likely to directly result</li> </ul>
115, 116	Subsection 32BB(6) (defence)	(i) the quality, safety or efficacy of the biological; or (ii) a matter relating to the labelling or packaging of the biological; or (iii) the improper use of the biological	<ul style="list-style-type: none"> <li>• is not likely to directly result</li> <li>• would not be likely to directly result</li> </ul>
123, 124	Subsection 32BC(6) (defence)	(i) the quality, safety or efficacy of the biological; or (ii) a matter relating to the labelling or packaging of the biological; or (iii) the improper use of the biological	<ul style="list-style-type: none"> <li>• is not likely to directly result</li> <li>• would not be likely to directly result</li> </ul>



Item(s)	Provision	Nature of linkage	Additional aggravating elements
130, 131	Subsection 32BD(6) (defence)	(i) the quality, safety or efficacy of the biological; or (ii) a matter relating to the labelling or packaging of the biological; or (iii) the improper use of the biological	<ul style="list-style-type: none"> <li>is not likely to directly result</li> <li>would not be likely to directly result</li> </ul>
142	Paragraph 32CJ(6)(e)	the person failed to comply with that requirement.	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
147	Paragraph 32CN(1)(e)	(i) the supply is not in accordance with the authority; or (ii) the supply is not in accordance with the conditions to which the authority is subject; or (iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6)	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
152	32CN(5)(f)	(i) the supply is not in accordance with those rules; or (ii) the supply is not in the circumstances specified in those rules; or (iii) the supply is not in accordance with the conditions specified in those rules	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
182	Paragraph 35(1)(e)	the person carried out the step in the manufacture of the goods.	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
187	Paragraph 35(5)(f)	the person carried out the step in the manufacture of the goods.	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
221	Paragraph 41MA(1)(e)	the device does not comply with the essential principles	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>
226	Paragraph 41MA(5)(e)	the device does not comply with the essential principles.	<ul style="list-style-type: none"> <li>is likely to result</li> <li>would be likely to result</li> </ul>

Item(s)	Provision	Nature of linkage	Additional aggravating elements
232	Paragraph 41MA(9)(e)	the device does not comply with the essential principles.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
243	Paragraph 41ME(1)(e)	the conformity assessment procedures have not been applied to the device.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
248	Paragraph 41ME(5)(e)	the conformity assessment procedures have not been applied to the device.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
252	Paragraph 41MF(1)(d)	the conformity assessment procedures have not been applied to the device.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
256	Paragraph 41MF(3)(d)	the conformity assessment procedures have not been applied to the device.	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
262, 263	Subsection 41MI(7) (defence)	<ul style="list-style-type: none"> <li>(i) the quality, safety or performance of the medical device; or</li> <li>(ii) a matter relating to the labelling or packaging of the medical device; or</li> <li>(iii) the improper use of the medical device</li> </ul>	<ul style="list-style-type: none"> <li>• is not likely to directly result</li> <li>• would not be likely to directly result</li> </ul>
273	Paragraph 41MO(1)(d)	<ul style="list-style-type: none"> <li>(i) the supply is not in accordance with the authority; or</li> <li>(ii) the supply is not in accordance with the conditions to which the authority is subject; or</li> <li>(iii) the supply is not in accordance with regulations made for the purpose of subsection 41HC(5)</li> </ul>	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>

Item(s)	Provision	Nature of linkage	Additional aggravating elements
278	Paragraph 41MO(4A)(f)	(i) the supply is not in accordance with those rules; or (ii) the supply is not in the circumstances specified in those rules; or (iii) the supply is not in accordance with the conditions specified in those rules	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>
287	Paragraph 42V(6)(c)	the person failed to comply with a requirement in subsection 42V(1) relating to the recovery of therapeutic goods that have been, or may have been, tampered with	<ul style="list-style-type: none"> <li>• is likely to result</li> <li>• would be likely to result</li> </ul>

**Table 3—Changes to strict liability offences**

Item(s)	Nature of offence	Repealed subsections	New subsections
6, 7	False statements in requests for variation of entries in the Register	• 9G(2) and (3)	• 9G(5) and (6)
12, 14	Importing therapeutic goods that do not comply with standards	• 14(2) and (3)	• 14(4A) and (4B)
21, 22	Supplying therapeutic goods that do not comply with standards	• 14(7) and (8)	• 14(9AA) and (9AB)
27, 28	Exporting therapeutic goods that do not comply with standards	• 14(11) and (12)	• 14(13AA) and (13AB)
32, 33	Act or omission breaching a condition of Secretary's consent under section 14 or 14A	• 15(3) and (4)	• 15(6) and (7)
36, 37	Importing, exporting, manufacturing or supplying therapeutic goods that are not in the Register and not covered by an exemption, approval or authority	• 19B(2) and (3)	• 19B(4A) and (4B)
46, 47	False or misleading statement in certification for listing of certain medicines under section 26A or 26BA	• 21A(2) and (3)	• 21A(4A) and (4B)

Item(s)	Nature of offence	Repealed subsections	New subsections
49, 50	Act or omission breaching a condition of registration or listing of therapeutic goods	· 21A(6) and (7)	· 21A(8A) and (8B)
55	Supplying therapeutic goods under an authority (s 19(5)), except in accordance with the authority, conditions or regulations	· 21A(10) and (11)	· 21A(10) and (11) <sup>5</sup>
63	Using therapeutic goods (other than registered, listed or exempt goods) not in accordance with approval or authority under section 19 or conditions applicable under subsection 19(4A)	· 21A(13) and (14)	· 21A(13) and (14) <sup>6</sup>
67, 68	False statements in applications for registration under Part 3-2	· 22A(2) and (3)	· 22A(5) and (6)
71, 72	Failure to comply with requirements relating to public notification and recall of therapeutic goods	· 30EC(2) and (3)	· 30EC(5) and (6)
76, 77	Failure to comply with a notice under subsection 30F(2) (relating to goods that are exempt under section 18A and do not conform to standards etc.)	· 30F(4C) and (4D)	· 30F(6) and (6A)
83	False or misleading response in purported compliance with a notice under section 31	· 31(5B) and (5C)	· 31(7) and (8) <sup>7</sup>
105, 106	Importing a biological that is not in the Register and not covered by an exemption, approval or authority	· 32BA(2) and (3)	· 32BA(4A) and (4B)
112, 113	Exporting a biological that is not in the Register and not covered by an exemption, approval or authority	· 32BB(2) and (3)	· 32BB(4A) and (4B)
120, 121	Manufacturing a biological that is not in the Register and not covered by an exemption, approval or authority	· 32BC(2) and (3)	· 32BC(4A) and (4B)
127, 128	Supplying a biological that is not in the Register and not covered by an exemption, approval or authority	· 32BD(2) and (3)	· 32BD(4A) and (4B)
137, 139	Using biologicals not in the Register and not subject to exemption or approvals	· 32BI(2) and (3)	· 32BI(5) and (6)
148, 149	Supplying a biological under an authority (s 32CM(1)), except in accordance with the authority, conditions or regulations	· 32CN(2) and (3)	· 32CN(4A) and (4B)

<sup>5</sup> Item 55 also inserts subsection 21A(9A) as the equivalent fault-based offence (without an aggravating element). This offence is currently located at subsection 22(7A) (see also item 64).

<sup>6</sup> Item 63 also inserts subsection 21A(12A) as the equivalent fault-based offence (without an aggravating element). This offence is currently located at subsection 22(8) (see also item 64).

<sup>7</sup> Item 83 also replaces the existing fault-based offence at subsection 31(6) with a similar offence in the equivalent format to subsections 31(5A) and (7).

Item(s)	Nature of offence	Repealed subsections	New subsections
158, 160	False statements in applications for including biologicals in the Register	· 32DO(2) and (3)	· 32DO(5) and (6)
162, 164	Act or omission in breach of conditions of including a biological in the Register	· 32EF(2) and (3)	· 32EF(5) and (6)
166, 168	Failure to comply with requirements relating to public notification and recall of biologicals	· 32HC(2) and (3)	· 32HC(5) and (6)
172, 174	False or misleading information or documents in purported compliance with a notice under section 32JA	· 32JB(3) and (4)	· 32JB(6) and (7)
183, 184	Manufacturing goods unless the goods or person is exempt or a manufacturing licence is in force	· 35(2) and (3)	· 35(4A) and (4B)
188, 189	Manufacturing goods that are exempt under section 18A or 32CB while not holding a manufacturing licence	· 35(7) and (8) <sup>8</sup>	· 35(10) and (11)
191, 192	Act or omission in breach of conditions of manufacturing licence by licence holder	· 35B(2) and (3)	· 35B(5) and (6)
195, 196	False statement in connection with an application for a conformity assessment certificate	· 41EI(2) and (3)	· 41EI(5) and (6)
200, 201	False statement in connection with an application to include a medical device in the Register or a certification under section 41FD	· 41FE(2) and (3)	· 41FE(5) and (6)
206, 207	False or misleading information in purported compliance with a notice under section 41JA	· 41JB(5) and (6)	· 41JB(8) and (9)
217, 218	Act or omission breaching requirements imposed under section 41KA public notification and recovery	· 41KC(2) and (3)	· 41KC(5) and (6)
222, 223	Importing a medical device that does not comply with essential principles without consent of the Secretary	· 41MA(2) and (3)	· 41MA(4A) and (4B)
227, 228	Supplying a medical device that does not comply with essential principles without consent of the Secretary	· 41MA(6) and (7)	· 41MA(8A) and (8B)
233, 235	Exporting a medical device that does not comply with essential principles without consent of the Secretary	· 41MA(10) and (11) <sup>9</sup>	· 41MA(13) and (14)
238, 239	Act or omission in breach of consent by Secretary relating to device essential principles	· 41MC(3) and (4)	· 41MC(6) and (7)

<sup>8</sup> Items 188 and 189 also repeal subsections 35(6) and (10), which currently apply strict liability to a single element of each of the fault-based offences in subsections 35(5) and (9), namely that the relevant goods are exempt under section 18A or 32CB.

<sup>9</sup> Item 235 also repeals the existing subsection 41MA(13) (see above).

Item(s)	Nature of offence	Repealed subsections	New subsections
244, 245	Supply of medical device by manufacturer without applying conformity assessment procedures	· 41ME(2) and (3)	· 41ME(4A) and (4B)
249, 250	Export of medical device by manufacturer without applying conformity assessment procedures	· 41ME(6) and (7)	· 41ME(9) and (10)
259, 260	Importing, exporting, manufacturing or supplying a medical device that is not in the Register and not covered by an exemption, approval or authority	· 41MI(2) and (3) <sup>10</sup>	· 41MI(5) and (5A)
266, 267	Act or omission breaching condition of inclusion of a medical device in the Register	· 41MN(2) and (3)	· 41MN(2) and (3)
269, 270	Act or omission breaching a condition of a conformity assessment certificate	· 41MN(6) and (7)	· 41MN(8A) and (8B)
274, 275	Supplying a medical device under an authority (s 41HC(1)), except in accordance with authority, conditions or regulations	· 41MO(2) and (3)	· 41MO(4AA) and (4AB)
283, 284	Using a medical device under an approval, except in accordance with the approval	· 41MO(6) and (7)	· 41MO(9) and (10)
288, 289	Failure to comply with recovery of goods subject to actual or potential product tampering	· 42V(6A) and (6B)	· 42V(6D) and (6E)

**Table 4—Additional strict liability offences**

Item(s)	Nature of offence	Amending provisions
42	Failure to notify Secretary about the manufacturer or manufacturing premises of goods that are exempt under section 18A	· Insert subsections 20(1BA) and (1BB)
78	Failure to comply with a section 31 notice from the Secretary seeking information or documents	· Insert subsection 31(4B) <sup>11</sup>
87	Failure to give information or documents sought by the Secretary by a notice under section 31A, 31AA, 31B or 31BA	· Insert subsections 31C(2) and (3)

<sup>10</sup> Item 260 also repeals the existing subsection 41MI(5), which currently applies strict liability to a single element of the fault-based offence in subsection 41MI(4), namely that the relevant device is not of a kind included in the Register, of a kind covered by an exemption, an exempt device, or the subject of an approval or authority.

<sup>11</sup> Item 79 amends subsection 31(5) to provide that the new offence in subsection 31(4B), and not the offence in subsection 31(4), is an offence of strict liability. Consistent with similar offences in sections 31C, 32JB, 32JI, 41JB and 41JG, the offence in subsection 31(4) becomes a fault-based offence.

Item(s)	Nature of offence	Amending provisions
88	Giving false or misleading information or documents in response to a notice under section 31A, 31AA, 31B or 31BA	· Insert subsections 31D(1A) and (1B)
95	Giving false or misleading documents in response to a notice under section 31A, 31AA, 31B or 31BA	· Insert subsections 31E(1A) and (1B)
135	Failure to notify Secretary regarding manufacturer or manufacturing premises of biologicals that are exempt under section 32CA	· Insert subsection 32BG(1A) and (1B)
169	Failure to comply with a notice under section 32JA seeking information or documents about biologicals	· Insert subsections 32JB(1B) and (1C) <sup>12</sup>
176	Failure to comply with a notice seeking information or documents under section 32JE, 32JF, 32JG or 32JH	· Insert subsections 32JI(1A) and (1B)
203	Failure to comply with a notice under section 41JA seeking information or documents about medical devices	· Insert subsections 41JB(3B) and (3C) <sup>13</sup>
211	Failure to comply with a notice seeking information or documents under section 41JCA, 41JD, 41JE, 41JF or 41JFA	· Insert subsections 41JG(2) and (3)
213	Giving false or misleading information in response to a notice under section 41JCA, 41JD, 41JE, 41JF or 41JFA	· Insert subsections 41JH(2) and (3)
214	Giving false or misleading documents in response to a notice under section 41JCA, 41JD, 41JE, 41JF or 41JFA	· Insert subsections 41JI(1A) and (1B)

**Table 5—Amendments to cross-references**

Item(s)	Affected Provision	Amendment
2	Section 5A	· Omit reference to subsection 21A(2) · Insert reference to subsection 21A(4A)
17	Subsection 14(5A)	· Omit reference to subsection 14(2) · Insert reference to subsection 14(4A)
23	Subsection 14(9A)	· Omit reference to subsection 14(7) · Insert reference to subsection 14(9AA)
29	Subsection 14(13A)	· Omit reference to subsection 14(11) · Insert reference to subsection 14(13AA)
30	Paragraph 14B(a)	· Omit references to subsections 14(2) and (11) · Insert references to subsections 14(4A) and (13AA)
38	Subsection 19B(5)	· Omit reference to subsection 19B(2) · Insert reference to subsection 19B(4A)
41	Paragraph 19B(7)(a)	· Omit reference to subsection 19B(2) · Insert reference to subsection 19B(4A)

<sup>12</sup> Item 169 also inserts subsection 32JB(1D), providing that subsection (1B) does not apply if the person has a reasonable excuse.

<sup>13</sup> Item 203 also inserts subsection 41JB(3D), providing that subsection (3B) does not apply if the person has a reasonable excuse.

Item(s)	Affected Provision	Amendment
43	Subsection 20(1C)	· Insert reference to subsection 20(1BA)
69	Subsection 30EA(1)	· Omit reference to subsection 19B(2) · Insert reference to subsection 19B(4A)
89, 90	Subsection 31D(2)	· Insert references to subsection 31D(1A)
92, 93	Subsection 31D(3)	· Insert references to subsection 31D(1A)
96	Subsection 31E(2)	· Insert reference to subsection 31E(1A)
98	Subsection 31E(3)	· Insert reference to subsection 31E(1A)
107	Subsection 32BA(5)	· Omit reference to subsection 32BA(2) · Insert reference to subsection 32BA(4A)
114	Subsection 32BB(5)	· Omit reference to subsection 32BB(2) · Insert reference to subsection 32BB (4A)
122	Subsection 32BC(5)	· Omit reference to subsection 32BC(2) · Insert reference to subsection 32BC(4A)
129	Subsection 32BD(5)	· Omit reference to subsection 32BD(2) · Insert reference to subsection 32BD(4A)
175	Paragraph 32JD(2)(d)	· Omit reference to subsection 32JB(3) · Insert references to subsections 32JB(1B) and (6)
179	Paragraph 32JK(2)(d)	· Insert references to subsections 32JI(1A) and (3)
197	Division 2 of Part 4-4 (note after heading)	· Omit reference to subsection 41MN(6) · Insert reference to subsection 41MN(8A)
202	Division 2 of Part 4-5 (note after heading)	· Omit reference to subsection 41MN(2) · Insert reference to subsection 41MN(4A)
208	Paragraph 41JC(2)(d)	· Omit reference to subsection 41JB(5) · Insert reference to subsection 41JB(8)
215	Subsection 41JI(2)	· Insert reference to subsection (1A)
240	Paragraph 41MD(a)	· Omit references to subsections 41MA(2) and (10) · Insert references to subsections 41MA(4A) and (13)
261	Subsection 41MI(6)	· Omit reference to subsection 41MI(2) · Insert reference to subsection 41MI(5)
264	Paragraph 41MJ(a)	· Omit reference to subsection 41MI(2) · Insert reference to subsection 41MI(5)



## **SCHEDULE 8 — Record-keeping etc.**

### ***Therapeutic Goods Act 1989***

This Schedule contains amendments to the Act to provide for record-keeping and reporting requirements in relation to biologicals that are included in the Register, to make them consistent with those e.g. for prescription medicines, which can pose similar risks to public health.

#### **Items 1, 2 and 3**

Subsection 32EA(1) of the Act provides that the inclusion of a biological in the Register is subject to certain conditions. Subparagraph 32EA(1)(a)(i) of the Act provides that it is a condition that the person in relation to whom the biological is included will allow an authorised person to enter premises at which that person or any other person deals with the biological.

Item 1 amends subparagraph 32EA(1)(a)(i) of the Act to extend this to premises at which the person, or any other person, complies with record-keeping conditions or keeps documents that relate to the biological.

Item 2 amends paragraph 32EA(1)(a) of the Act to add requirements to allow an authorised person, while on premises mentioned in subparagraph 32EA(1)(a)(i), to inspect, and make copies of, any records kept in compliance with paragraph 32EC(2)(c) or any documents that relate to the biological.

Item 3 amends subsection 32EA(1) of the Act to add a requirement to make any record kept in compliance with paragraph 32EC(2)(c) of the Act available to an authorised person for inspection.

The amendments made by these items make subsection 32EA(1) consistent with the equivalent conditions in subsection 28(5) in relation to therapeutic goods (such as medicines) that are registered or listed under Part 3-2 of the Act.

#### **Item 4**

Section 32EC of the Act provides that the inclusion of a biological in the Register is subject to the conditions set out in a determination under that section.

This item adds a power to determine conditions covering reporting requirements relating to the biological.

The amendment is consistent with paragraph 28(5)(e) of the Act, under which the regulations may prescribe reporting requirements in relation to therapeutic goods (such as medicines) that are registered or listed under Part 3-2 of the Act.

#### **Item 5**

This item makes a related amendment to section 46A of the Act (which deals with the powers of an authorised person to enter and search a range of premises including those of sponsors of biologicals that are included in the Register) with the effect of permitting authorised officers to search sponsors' premises that are connected with the keeping of records in accordance with the record-keeping requirements determined under section 32EC.

These amendments will enable authorised officers to enter premises where sponsors' records about their biologicals are kept but where the biologicals themselves are not dealt with – for example, if a sponsor has a number of sites where it undertakes a range of activities including a separate administrative centre where records are kept (section 32EA of the Act currently only allows authorised persons to enter premises where sponsors of biologicals deal with their biologicals).

### **Application**

#### **Item 6**

This item provides that the amendments made by this Schedule apply in relation to biologicals, regardless of whether the biologicals were included in the Register before, on or after the commencement of this item.

## **SCHEDULE 9 — Other amendments**

### ***Therapeutic Goods Act 1989***

This Schedule sets out a number of minor amendments to the Act, that are intended to either achieve greater consistency across the regulation of different kinds of therapeutic goods under the Act, reduce regulation, reduce health risks to the public or make other, minor changes.

#### **Items 1, 2, 18, 19, 32 and 33 (and subitems 38(1) and (2), 39(5) and (6) and 40(4) and (5))**

Subsections 19(1), 32CK(1) and 41HB(1) of the Act allow the Secretary to grant a written approval to a person for the importation, exportation or supply of specified therapeutic goods, or a specified biological or kind of medical device (other than therapeutic goods or a biological or device that is included in the Register) for use in the treatment of another person or for experimental purposes.

Items 1, 18 and 32 insert new subsections 19(1AA), 32CK(1A) and 41HB(1A) to restrict the persons to whom an approval under subsection 19(1), 32CK(1) and 41HB(1), respectively, relating to the use of goods in the treatment of another person can be granted. Such an approval would be able to be granted only to a health practitioner.

Items 2, 19 and 33 amend subsections 19(2), 32CK(3) and 41HB(4) to provide that, if the Secretary has approved an application form for approvals to import, export or supply specified therapeutic goods, or a specified biological or kind of medical device, for use in the treatment of another person, an application for such an approval must be in the approved form.

Subitems 38(1), 39(5) and 40(4) provide that the restrictions of the persons to whom approvals can be granted apply in relation to approvals granted on or after the commencement of items 38, 39 and 40, respectively.

Subitems 38(2), 39(6) and 40(5) provide that the requirements to use an approved application form (if one has been approved) apply in relation to applications made on or after the commencement of items 38, 39 and 40, respectively.

#### **Items 3, 20 and 34 (and subitems 38(3), 39(7) and 40(6))**

Subsections 19(5), 32CM(1) and 41HC(1) of the Act allow the Secretary to authorise a specified medical practitioner to supply specified therapeutic goods, or a specified biological or kind of medical device to a specified class of recipients.

Items 3, 20 and 34 insert new subsections 19(5AA), 32CM(1A) and 41HC(1A) to clarify that, if the Secretary has approved an application form for authorisations covered by subsection 19(5), 32CM(1) or 41HC(1), an application for such an authorisation must be in the approved form.

Subitems 38(3), 39(7) and 40(6) provide that the requirements to use an approved application form (if one has been approved) apply in relation to applications made on or after the commencement of items 38, 39 and 40, respectively.

**Items 4 and 35 (and subitems 38(4) and 40(7))**

Subsection 22(6) of the Act provides that it is an offence for a person to claim, by any means, that the person or another person can arrange the supply of therapeutic goods, other than registered goods, listed goods, exempt goods or goods that are exempt under section 18A. Section 41MM of the Act makes similar provision in relation to medical devices.

Items 4 and 35 repeal and replace subsection 22(6) and section 41MM consistent with subsection 32BJ(4), which is the equivalent provision in relation to biologicals. The amendments clarify that a person does not commit an offence by claiming to be able to arrange the supply of goods that the person can supply, or by claiming that another person can arrange the supply of goods that the other person can supply, if the goods are subject to any relevant exemption, approval or authority.

The amendments make subsection 22(6) and section 41MM.

Subitem 38(4) provides that the repeal and replacement of subsection 22(6) applies in relation to claims made on or after the commencement of item 38.

Subitem 40(7) provides that the repeal and replacement of section 41MM applies in relation to claims made on or after the commencement of item 40.

**Items 5 and 6 (and subitems 38(5) and (6))**

Subsection 28(5A) of the Act provides that it is a condition of the listing of a medicine under section 26A of the Act that the person in relation to whom the medicine is listed will, if the Secretary so requests, deliver a reasonable number of samples of the medicine in accordance with the request.

Items 5 and 6 repeal subsection 28(5A) and insert an equivalent condition in subsection 28(5) so that it applies to all therapeutic goods registered or listed under Part 3-2 of the Act.

Subitem 38(5) provides that subsection 28(5), as amended, applies in relation to therapeutic goods registered or listed before, on or after the commencement of item 38.

Subitem 38(6) provides that, despite the repeal of subsection 28(5A), that subsection, as in force immediately before the commencement of item 38, continues to apply in relation to a request referred to in that subsection that was made before the commencement of item 38.

**Item 7 (and subitem 38(7))**

Paragraph 29D(1)(b) of the Act provides that the Secretary may suspend the registration or listing of therapeutic goods under Part 3-2 of the Act if the Secretary is satisfied that it is

likely that there are grounds for cancelling the registration or listing of the goods under certain paragraphs of section 30 of the Act.

Consistent with the powers to suspend the inclusion of a biological or medical device in the Register, item 7 amends paragraph 29D(1)(b) to insert a reference to paragraph 30(1)(g) of the Act – that the Secretary is satisfied that a statement made in, or in connection with, the application for registration or listing of the goods was false or misleading in a material particular.

Subitem 38(7) provides that the amendment of paragraph 29D(1)(b) of the Act applies in relation therapeutic goods included in the Register before, on or after the commencement of item 38.

### **Item 8**

Subsection 30(3) of the Act requires the Secretary to give notice, and provide a reasonable opportunity to make submissions, before cancelling the registration or listing of therapeutic goods under subsection 30(2) of the Act, otherwise than as a result of a failure to pay the annual registration or listing charge.

Section 30 of the Act was amended by the *Therapeutic Goods (2016 Measures No. 1) Act 2017* to remove failure to pay the annual registration or listing charge as a ground for action under subsection 30(2) and make it a ground for action under subsection 30(1) instead.

Item 8 makes a consequential amendment by removing the exception from subsection 30(3) of the Act.

### **Items 9, 10, 11, 17 and 22 (and subitems 39(1), (2), (4) and (9))**

Sections 32BH and 32BI of the Act impose requirements in relation to biologicals. In each case, biologicals that are covered by an exemption, approval or authority under various provisions are excluded from the application of these requirements.

Section 32BK of the Act is a civil penalty provision prohibiting a person from making certain false representations about a biological, including that the biological is the subject of an authority under subsection 32CM(1) of the Act.

Section 32HA of the Act provides for the Secretary to impose requirements on persons supplying biologicals in certain circumstances, which vary depending, among other things, on whether the biological is the subject of an authority under subsection 32CM(1) of the Act.

Amendments made by the *Therapeutic Goods (2016 Measures No. 1) Act 2017* provided for authorities set out in rules under subsection 32CM(7A) of the Act, in addition to those under subsection 32CM(1).

Items 9, 10, 11, 17 and 22 amend sections 32BH, 32BI, 32BK and 32HA of the Act to clarify that they apply in relation to authorities under subsection 32CM(7A) rules as well as authorities granted under subsection 32CM(1).

Subitems 39(1), (2) and (4) provide that the amendments of sections 32BH, 32BI and 32BK of the Act apply, respectively, in relation to supplies of a biological occurring, uses of a biological and representations made on or after the commencement of item 39.

Subitem 39(9) provides that the amendments of section 32HA of the Act apply in relation to supplies of a biological occurring on or after the commencement of item 39.

### **Items 12, 13, 14, 15 and 16 (and subitem 39(3))**

Subsection 32BJ(4) of the Act provides that a person must not claim that the person, or another person, can arrange the supply of a biological except in certain circumstances. Those circumstances include that the biological is included in the Register in relation to the person, that the person is exempt under subsection 32CA(1) or that the biological is the subject of an approval under subsection 32CK(1) or 32CO(1), (1A) or (2) that is held by the person.

Items 12, 13, 14, 15 and 16 amend subsection 32BJ(4) with the effect that a person can claim that another person can arrange the supply of a biological if the biological is included in the Register in relation to the other person, the other person is exempt under subsection 32CA(1) or the biological is the subject of an approval under subsection 32CK(1) or 32CO(1), (1A) or (2) that is held by the other person.

Item 12 amends subparagraph 32BJ(4)(b)(i) with the effect that, in the case of biologicals that are included in the Register, a claim of ability to arrange supply is not restricted to the person in relation to whom the biologicals have been so included, and a person can claim to be able to arrange the supply of a biological if it is included in the Register in relation to another person.

Items 13, 14 and 16 amend subparagraphs 32BJ(4)(b)(ii), (iv) and (vi), respectively, to insert references to the other person. This will enable a person to claim that another person can supply biologicals if the other person is exempt or holds an approval or authority.

Currently, subparagraph 32BJ(4)(b)(v) provides that a person can claim that the person, or another person, can arrange the supply of a biological if the biological is the subject of an authority under subsection 32CM(1) that is held by the person. Item 15 amends subparagraph 32BJ(4)(b)(v), both:

- to insert a reference to the other person, consistent with the amendments of subparagraphs 32BJ(4)(b)(ii), (iv) and (vi) made by items 13, 14 and 16, and
- to insert a reference to an authority under subsection 32CM(7A), similar to the amendments of sections 32BH, 32BI, 32BK and 32HA made by items 9, 10, 11, 17 and 22.

Subitem 39(3) provides that the amendments of section 32BJ of the Act apply in relation to claims made on or after the commencement of item 39.

### **Items 21 and 31 (and subitems 39(8) and 40(3))**

Items 21 and 31 amend sections 32FA and 41GA of the Act to remove the power to suspend the inclusion of a biological or medical device in the Register on the basis of non-payment of annual charge.

Amendments made to the Act by the *Therapeutic Goods (2016 Measures No. 1) Act 2017* enable the Secretary to revoke the cancellation of an entry in the Register on the basis of non-payment of annual charge, where the charge is subsequently paid. Following these amendments, suspension of an entry in the Register on this ground is unnecessary. This brings the suspension provision for biologicals into line with the treatment of registered and listed goods; there is no provision to suspend the registration or listing of a therapeutic good under Part 3-2 of the Act on this ground.

Subitem 39(8) provides that the amendment of paragraph 32FA(1)(b) of the Act applies in relation to suspensions made on or after the commencement of item 39.

Subitem 40(3) provides that the amendment of paragraph 41GA(1)(b) of the Act applies in relation to suspensions made on or after the commencement of item 40.

### **Items 23, 24, 25 and 26**

Section 40B of the Act provides for the variation of manufacturing licences, on application by the licence holder, to add additional manufacturing sites or to vary manufacturing site authorisations.

Items 23, 24, 25 and 26 amend section 40B to provide for the variation of manufacturing licences to remove manufacturing sites.

Item 23 inserts new subsections 40B(9A) to (9D).

New subsection 40B(9A) allows the holder of a licence to apply for a variation of the licence so that it ceases to cover one or more specified manufacturing sites.

New subsection 40B(9B) sets out requirements that must be met in relation to an application.

New subsection 40B(9C) provides that, if an application is made under subsection 40B(9A), the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that it ceases to cover each specified manufacturing site.

New subsection 40B(9D) provides that a variation takes effect on the day specified in the notice.

Items 24, 25 and 26 make consequential amendments to subsections 40B(10) and (11).

### **Items 27, 28, 29 and 30 (and subitems 40(1) and (2))**

Section 41EC of the Act sets out the process for considering applications for conformity assessment certificates. Section 41FI of the Act sets out the process for auditing applications for the inclusion of a kind of medical device in the Register. Sections 41EG and 41FK of the Act set out circumstances in which applications lapse, and refer to requirements by the Secretary to deliver samples of the kind of medical device to which the application relates. However, there is currently no provision in section 41EC or 41FI for the Secretary to impose such a requirement.

Items 27 and 29 amend sections 41EC and 41FI, respectively, to allow the Secretary to require the applicant to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates.

Items 28 and 30 make consequential amendments to sections 41EG and 41FK to refer to the provisions inserted into sections 41EC and 41FI.

Subitems 40(1) and (2) provide that the amendments of sections 41EC, 41EG, 41FI and 41FK apply in relation to applications made on or after the commencement of item 40 and applications pending immediately before the commencement of that item.

### **Items 36 and 37**

Section 46A of the Act provides that an authorised person may enter certain premises and exercise powers of search and inspection to find out whether the Act or the regulations have been complied with. Those premises include premises of persons who have been granted approvals or authorities under section 19, 41HB or 41HC of the Act.

Consistent with the treatment of authorities under section 32CM, for which section 46A refers only to subsection 32CM(1), items 36 and 37 amend section 46A to limit the references to sections 19, 41HB and 41HC to subsections 19(1) and (5), 41HB(1) and 41HC(1). This clarifies that the section does not apply to premises of persons who are authorised to supply goods under rules made under subsection 19(7A) or 41HC(6).