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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS AMENDMENT (2020 MEASURES NO. 1) BILL 2020

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health, the Hon Greg Hunt MP)

THERAPEUTIC GOODS AMENDMENT (2020 MEASURES NO. 1) BILL 2020

OUTLINE

The Therapeutic Goods Amendment (2020 Measures No. 1) Bill 2020 (the Bill) makes a number of amendments to the *Therapeutic Goods Act 1989* (the Act).

These amendments:

a) align the definition in the Act of 'medical device', and of a number of other device-related definitions, more closely with the equivalent definitions in the European Union (the EU), to support the harmonisation of the regulatory scheme for medical devices in Australia with international jurisdictions like the EU;
b) enable the Secretary to provide early, scientific advice to sponsors of registrable medicines about prescribed aspects of the safety, quality or efficacy of their medicines, before they apply for marketing approval, to assist sponsors to better understand the level and nature of information needed to support a successful application for marketing approval, and to reduce delays in accessing new medicines for Australian consumers;
c) introduce a targeted data protection regime for assessed listed medicines, in relation to clinical trial data that supports an indication (these are statements about a product's therapeutic use) for such medicines, to foster innovation in Australia's complementary medicines industry; and
d) make a number of more minor amendments, principally to reduce regulatory burden (including to remove an unintended barrier to access for provisionally registered medicines), improve consistency or make other more minor amendments and corrections.

Financial Impact Statement

There are no financial implications for the Government's budget. Implementation of measures will be funded through the TGA's current cost recovery mechanisms, under which the costs of administering the Act are fully recovered from industry.

Statement of Compatibility with Human Rights

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

THERAPEUTIC GOODS AMENDMENT (2020 MEASURES NO. 1) BILL 2020

This 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

The Therapeutic Goods Amendment (2020 Measures No. 1) Bill 2020 (the Bill) makes a number of amendments to the *Therapeutic Goods Act 1989* (the Act).

These amendments will:

a) align the definition in the Act of 'medical device', and of a number of other device-related definitions, more closely with the equivalent definitions in the European Union (EU), to support the harmonisation of the regulatory scheme for medical devices in Australia with international jurisdictions like the EU;
b) enable the Secretary to provide early, scientific advice to sponsors of registrable medicines about prescribed aspects of their safety, quality or efficacy, before they apply for marketing approval, to assist sponsors to better understand the level and nature of information needed to support a successful application for marketing approval, and to reduce delays in accessing new medicines for Australian consumers;
c) introduce a targeted data protection regime for assessed listed medicines, in relation to clinical trial data that supports an indication (these are statements about a product's therapeutic use) for such medicines, to foster innovation in Australia's complementary medicines industry: and
d) make a number of more minor amendments, principally to reduce regulatory burden (including to remove an unintended barrier to access for provisionally registered medicines), improve consistency or make other more minor amendments and corrections.

Human rights implications

This instrument engages the right to health in Article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR).

Right to Health

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In General Comment No.14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as a right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Bill takes several positive steps to promote the right to health, by the introduction in particular of measures designed to reduce delay for Australian consumers to access new therapeutic goods and to support the safety of Australian consumers, by:

- bringing Australia's regulatory scheme for medical devices more closely into line with that of the EU;
- enabling the Secretary to provide early scientific advice to sponsors of registrable medicines (these are principally higher risk, prescription and over the counter medicines) about prescribed aspects of the quality, safety or efficacy of such products, to assist them to better understand the level and nature of supporting information needed for a successful application for marketing approval;
- removing an unintended barrier to accessing the provisional registration pathway for promising new medicines;
- avoiding unnecessary delays for sponsors of approved clinical trials; and
- removing an unintended barrier to efforts to alleviate the effects of shortages of medicines and other therapeutic goods.

In so doing, the Bill addresses the right to health in particular in relation to the availability and quality of therapeutic goods.

In particular, the measures to enable the Secretary to provide early scientific advice to sponsors of registrable medicines about their products is designed to assist them to avoid delays and rejections in connection with applications for marketing approval for such products, allowing these medicines to be more readily available for Australian consumers.

The measures in the Bill to remove an unintended barrier to accessing the provisional registration pathway for promising new medicines are also designed to address this aspect of the right to health. They remove an unnecessary regulatory step that may cause considerable delay for Australian consumers and health practitioners in accessing such medicines that provide a major therapeutic advance and are for the treatment of very serious conditions.

The measures in the Bill to remove a criminal offence that may be a disincentive for sponsors of potential alternative products to a medicine (or other therapeutic good) affected by a shortage from identifying if they are able to arrange the supply of their products to help alleviate the effects of the shortage also address the availability aspect of the right to health.

Conclusion

The Bill is compatible with human rights because it promotes the right to health, as outlined above.

The Hon Greg Hunt MP, Minister for Health

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NOTES ON CLAUSES

Clause 1 – Short Title
This clause provides that the Bill, once enacted, may be cited as the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020*.

Clause 2 – Commencement
This clause provides the timetable for the commencement of various provisions contained in the Bill:

- sections 1 to 3 commence on the day that the Bill receives Royal Assent;
- Part 1 of Schedule 1 commences on the later of 25 August 2020 (three months after the commencement of the new European Union regulations for medical device regulation) and the 28th day after the Bill receives Royal Assent (this will allow time for the making of regulations to update medical device-related definitions in the *Therapeutic Goods (Medical Devices) Regulations 2002*);
- Parts 2 to 4 of Schedule 1 commence on the day after the Bill receives Royal Assent;
- Schedules 2 to 4 commence on the 28th day after the Bill receives Royal Assent (to allow the making of regulations, and the approval of forms, to support measures in these schedules); and
- Schedules 5 to 10 commence on the day after the Bill receives Royal Assent.

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.

This is a technical provision which gives operational effect to the amendments contained in the Schedules. Schedules 1 to 10 amend the *Therapeutic Goods Act 1989*. Schedule 10 also includes a minor, consequential amendment to the *Patents Act 1990*.

SCHEDULE 1—MEDICAL DEVICES

Summary

On 5 April 2017, the EU adopted two new regulations to introduce significant reforms for medical devices and in vitro diagnostic medical devices, to better address the technological and scientific developments that have occurred in the devices sector over the last 20 years:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) (the EU Regulations); and
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746) (the EU IVD Regulations).

These regulations entered into force in the EU on 25 May 2017 and, through various transitional arrangements, will commence on 26 May 2020 for the EU Regulations and on 26 May 2022 for the EU IVD Regulations.

Recommendation 20 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review) recommended that, wherever possible and appropriate, the regulation of medical devices in Australia should align with the EU framework.

To support the implementation of Recommendation 20, the measures in this Schedule of the Bill amend a number of device-related definitions in the Act to more closely align with the EU Regulations, and to modernise the terminology of the Act in a similar manner to the EU approach.

The measures in this Schedule of the Bill also clarify the requirements relating to certifications made by persons applying for marketing approval for Class I (lowest risk) medical devices, improve the consistency of cancellation powers for medical devices with those for other therapeutic goods under the Act and improve the flexibility of optional medical device and conformity assessment standards.

Part 1—Medical device definitions

Therapeutic Goods Act 1989

Item 1 – Subsection 3(1) (definition of *accessory*)

This item amends the definition of 'accessory' in subsection 3(1) of the Act to make it clear that this term includes a thing that, when used with another device, assists that other device to be used as its manufacturer intended (under paragraph 41BD(1)(b) of the Act, an accessory is a medical device). This amendment is designed to bring this definition in the Act into alignment with the EU definition.

Item 2 – Paragraph 7B(1)(b)

Paragraph 7B(1)(b) of the Act provides that one of the criteria for a package containing one or more goods to constitute a kit under section 7B is if the package and the goods do not constitute a composite pack or a system or procedure pack.

The reference to system or procedure packs in paragraph 7B(1)(b) of the Act is unnecessary because paragraphs 7B(1)(c) and (d) separately make it clear that a

package containing one or more goods will only constitute a kit if at least one of the goods is a therapeutic good that falls into one of the categories listed in subparagraphs 7B(1)(d)(i)-(iv). This list does not include medical devices, and as subsection 41BF(2) makes it clear that system or procedure packs are medical devices, there is no need for the reference in paragraph 7B(1)(b) to such products.

This item therefore removes this reference to system or procedure packs, to avoid possible confusion.

Items 3- 7 – Paragraphs 41BD(1)(a), subparagraphs 41BD(1)(a)(i), (iii) and (iv)
These items make a number of amendments to the definition of a 'medical device' in section 41BD of the Act, to bring the express scope of this definition more clearly into line with the EU definition of this term.

In particular:

- item 3 amends paragraph 41BD(1)(a) of the Act to make it clear that software, implants and reagents are medical devices if they are used for human beings for one or more of the purposes mentioned in subparagraphs 41BD(1)(a)(i)-(v) (examples of such devices may include software that is a medical device for use in relation to diagnosing or screening for a disease or condition; implants such as joint replacement medical devices; and chemical solutions such as a stain that can be used in histopathology);
- item 4 amends subparagraph 41BD(1)(a)(i) of the Act to make it clear that an instrument, apparatus, appliance, software, implant, reagent, material or other article is a medical device if it is used for human beings for the 'prediction' or 'prognosis' of disease (examples of such devices include genetic tests to predict a patient's risk of developing a particular disease);
- item 5 amends subparagraph 41BD(1)(a)(iii) of the Act to make it clear that an instrument, apparatus, appliance, software, implant, reagent, material or other article is a medical device if it is used for human beings for the investigation, replacement or modification of a 'physiological or pathological process or state';
- item 6 amends subparagraph 41BD(1)(a)(iv) of the Act to make it clear that an instrument, apparatus, appliance, software, implant, reagent, material or other article is a medical device if it is used for human beings for the support of conception (examples of such devices include fertility and ovulation tests).
- item 7 introduces a new subparagraph 41BD(1)(a)(v), to make it clear that an instrument, apparatus, appliance, software, implant, reagent, material or other article is a medical device if it is used for human beings for the in vitro examination of a specimen derived from the human body for a specific medical purpose (examples include pregnancy tests and blood glucose monitoring). It is important to note that such products will only be medical devices if they are for a specific medical purpose – products that are used for educational or law enforcement purposes, such as police breathalysers, would not be captured by subparagraph 41BD(1)(a)(v).

The closer alignment of the Australian medical devices regulatory framework with the EU regulatory framework is designed to minimise actual and apparent differences between the two frameworks, and in so doing to reduce the delay for Australian consumers in accessing new medical devices.

Items 8 – 17 Paragraphs 41BD(1)(aa), (ab) and (b) and subsections 41BD(2), (2A), (2B) and (3)
These items make a number of minor, consequential amendments to paragraphs 41BD(1)(aa), (ab) and (b), and subsections 41BD(2), (2A), (2B) and (3) of the Act, to reflect the amendments made by item 3, and to include a reference to system or procedure pack in section 41BD to better highlight that these products are medical devices (this is currently stated in subsection 41BF(2) of the Act, separately to the main provision of the Act that deals with the range of products that may be devices).

Item 18 – Section 41BF
Subsection 41BF(1) of the Act currently sets out that a package and therapeutic goods in the package are a system or procedure pack if the criteria listed in paragraphs 41BF(1)(a)-(c) are all met. Subsection 41BF(2) of the Act currently makes it clear that system or procedure packs are medical devices.

This item repeals section 41BF of the Act and replaces it with a new section 41BF containing an updated definition of 'system or procedure pack'. The updated definition clarifies a number of aspects of the current definition of 'system or procedure pack' in section 41BF, and is designed to more closely align this term with the 'system' and 'procedure pack' definitions in Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) (the EU Regulations) - combining the scope of both these definitions in the updated definition of 'system or procedure pack'.

Under the updated definition, two or more goods will be a system or procedure pack if:

- at least one of the goods is a medical device; and
- either:
    - all of the goods are to be interconnected or combined for use in a medical or surgical procedure (i.e. regardless of whether the goods or some of the goods are packaged together or not); or
    - all of the goods are packaged together for use in a medical or surgical procedure (i.e. regardless of whether the goods or some of the goods are to be interconnected or combined for use in the medical or surgical procedure).

Goods that are interconnected or combined for use, or packaged together, but not for the purpose of being used in a medical or surgical procedure, would not constitute a system or procedure pack.

Part 2—Basis of certification of conformity assessment procedures

Therapeutic Goods Act 1989
Items 19 – 21 - Section 41FDA and application provision
Under section 41FD of the Act, when a person (an applicant) applies to include a kind of medical device in the Register they must certify as to a range of matters, including that their kind of device complies with the essential principles.

Under section 41FDA of the Act, when making this certification an applicant must also state the basis of the certification, from the matters listed in paragraphs 41FDA(a)-(c). This is not considered necessary for Class I medical devices, as these are lower risk products, and item 20 therefore amends section 41FDA to clarify that this requirement does not apply in relation to such devices.

Item 19 makes a minor editorial change to accommodate item 20, and item 21 makes it clear that the amendments made by this Part apply in relation to an application for inclusion in the Register made on or after the commencement of that item.

Part 3— Cancellation of entries of kinds of medical devices from the Register

Therapeutic Goods Act 1989

Item 22 – After paragraph 41GL(c)

This item introduces new paragraph (ca) to section 41GL of the Act to enable the Secretary to cancel a kind of medical device from the Register if the kind of medical device is exempt under paragraph 41HA(1)(b) of the Act.

This is to bring the cancellation powers for medical devices into line with the grounds for cancellation that are already provided for in the Act in relation to medicines and biologicals, and will also support the integrity of the Register as a record of therapeutic goods that are required to have, and that have been granted, marketing approval.

Item 23 – Application provision

This item provides that the amendment to include new paragraph (ca) in section 41GL of the Act applies to kinds of medical devices included in the ARTG before, on or after commencement of this Schedule.

Part 4—Medical device standards and conformity assessment standards

Therapeutic Goods Act 1989

Items 24 and 25 – At the end of section 41CB and at the end of section 41DC

These items insert new subsection (3) in section 41CB of the Act and new subsection (4) in section 41DC of the Act. New subsections 41CB(3) and 41DC(4) provide that an order made under subsection 41CB(1) or 41DC(1), being a medical device standards order or a conformity assessment standards order respectively, may apply, adopt or incorporate (with or without modification) any matter contained in an instrument or other writing as in force or existing from time to time.

These amendments would provide an express contrary intention to the application of subsection 14(2) of the *Legislation Act 2003* in relation to these legislative instruments, to enable them to adopt other documents as in force or existing from time to time. For example, this would enable a medical device standards order or a conformity assessment standards order to refer to an International Organization for Standardization (ISO) standards in this manner.

It is important to note that compliance with these legislative instruments is optional, not mandatory, for sponsors and manufacturers of medical devices.

Section 41CB of the Act enables the Minister to, by legislative instrument, make an order determining that matters specified in the order constitute a medical device standard for the kinds of devices identified in the order, with the effect that (as made clear by paragraph 41CB(1)(b) of the Act) any medical device of that kind will be taken to comply with those parts of the essential principles specified in the order.

The essential principles are requirements set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations), under section 41CA of the Act, that comprise minimum benchmarks of safety and performance for medical devices. An applicant for marketing approval for a kind of medical device must certify that their kind of device complies with the essential principles, and marketing approval may be cancelled if the Secretary is satisfied that this certification was not, or is no longer, correct in a material particular.

The purpose of a medical device standards order made under section 41CB is to provide medical device manufacturers and sponsors with a flexible option of demonstrating that their kind of device complies with the essential principles, or with particular parts of the essential principles, through the use of relevant international benchmarks. If a device manufacturer or sponsor can demonstrate that their device complies with the order, then the device will be taken to comply with the essential principles specified in the order.

Orders made by the Minister under section 41DC of the Act are designed to serve the same purpose in respect of the conformity assessment procedures, which are a separate set of requirements relating to minimum benchmarks for the safe manufacture of medical devices.

In relation to the adoption of other instruments in these orders from time to time, this is designed principally to ensure the currency of these orders, and to support their consistency with requirements for medical device manufacturers and sponsors in major international jurisdictions like the EU and the US (noting in particular that most medical devices supplied in Australia are manufactured overseas).

Without the ability for the Minister to adopt such instruments as in force from time to time, the value of these orders as flexible, optional compliance mechanisms for manufacturers and sponsors may erode quite quickly over time, as their elements fall out of step with later editions of the instruments.

In relation to accessing the instruments and other writings that may be adopted, in some instances these may be available for free, for example if they are European regulations, but in other instances they may not – for example standards published by the International Organisation for Standardization.

However, it is anticipated that the persons most affected by the adoption of such instruments – manufacturers and sponsors of medical devices – would be in possession of these documents in order to manufacture their products (including in relation to the manufacture of devices that are also supplied in other countries).

In addition, by prior written arrangement with the Department, a copy of an ISO or similar instrument that is adopted may also be made available for viewing free of charge at a Department's office in the Australian Capital Territory.

Significant care would also be taken before any proposed adoption of an ISO or similar instrument as in force from time to time, to ensure that any such action was the subject of considerable, informed consultation, in particular with affected industry, before the making of a medical device standards order or conformity assessment standards order along such lines.

SCHEDULE 2—SCIENTIFIC ADVICE ABOUT QUALITY, SAFETY AND EFFICACY OF MEDICINE

Summary
The measures in this Schedule of the Bill amend the Act to enable the Secretary to provide early, scientific advice to a person (in practice, this is likely to be medicine sponsors) about the safety, quality or efficacy of a registrable medicine (these are higher risk, mostly prescription and over the counter medicines).

To register a new medicine in the Australian Register of Therapeutic Goods (the Register), a person must submit an application for registration to the Secretary, with sufficient supporting information that demonstrates that the medicine meets appropriate standards of quality, safety and efficacy. The Therapeutic Goods Administration (the TGA) has a number of publically available guidance documents to assist sponsors to understand the accompanying information that is likely to be needed to support a successful application for registration.

However, the diversity of products that may be the subject of an application for registration means that in some instances, sufficient guidance on complex products may not be available, and guidance may not cover every possible scenario. Currently, precise, targeted regulatory advice on whether requirements have been met cannot be provided until the details of products and their supporting evidence are known, after an application has been submitted. Uncertainties about the level and nature of supporting information may risk sponsors investing considerable time and resources into developing supporting evidence that is not required, or missing data that is needed. In either instance, this may delay access to new medicines for consumers.

The measures in this Schedule of the Bill address such concerns by introducing a pathway for sponsors to request the Secretary for early scientific advice about certain aspects of the quality, safety or efficacy of a registrable medicine, before an application for registration is submitted.

Therapeutic Goods Act 1989
Item 1 – After Division 1A of Part 3-2
This item amends the Act to introduce new Division 1B in Part 3-2 of the Act, in relation to the provision by the Secretary of scientific advice about aspects of the safety, quality, or efficacy of a registrable medicine. New Division 1B comprises new section 22G, which establishes a process for potential applicants for the registration of a medicine to seek advice about certain aspects of the safety, quality or efficacy of their medicine before they apply for marketing approval.

New subsections 22G(1) to (6) allow a person to request the Secretary for advice about whether, if the person were to make an application under section 23 of the Act for the registration of a medicine, a prescribed aspect of the medicine's quality, safety or efficacy has been satisfactorily established for the purposes for which the medicine may be used (as identified by the person).

Under new subsections 22G(2), (4) or (6), each such request must relate only to one aspect of safety, quality or efficacy (though nothing would preclude a person from making more than one such request).

New subsection 22G(7) makes it clear that the Secretary must give advice in response to such a request that is made in accordance with section 22G.

New subsection 22G(8) sets out that such requests must be made in accordance with the form approved by the Secretary and be accompanied by the prescribed fee for such requests (paragraph 22G(8)(c) also provides that such requests may be accompanied by any information or documents the person making the request considers appropriate).

The purpose of the advice is to assist prospective section 23 applicants who are developing potential applications for the registration of a medicine to better understand the requirements around the level and nature of supporting information and evidence needed to support an application.

In some instances, it can be difficult for medicine sponsors to determine the level and nature of such information – for example, in relation to when a bioequivalence study is needed for a generic prescription medicine (this is a medicine based on an existing "innovator" medicine), or what is needed to justify not including such a study in applications involving such products.

Bioequivalence studies show that the rate and extent of absorption of a generic medicine's active ingredient in a patient's blood is the same as that of the innovator medicine. In certain circumstances, a bioequivalence study may not be needed to support an application for the registration of a generic prescription medicine – such as if physical and chemical testing can instead be used to show that the generic and the innovator medicine to which it relates are equivalent.

Uncertainty about when this is likely to be the case may risk medicine sponsors investing considerable time and resources into developing supporting evidence that is not required, or omitting data that is needed. In either instance, this may delay consumer access to new medicines, particularly if insufficient evidence results in an application for registration being rejected.

The introduction of section 22G is designed to address these concerns and reduce the risk of such delays, by enabling the Secretary to provide non-binding advice to sponsors to improve clarity around these complex technical problems. This will support the timely availability of therapeutic goods in Australia.

It is expected that initially the aspects of a registrable medicine's safety, quality or efficacy that will be prescribed for the purposes of the new provision will focus on

bioequivalence issues and, in particular, when the absence of bioequivalence studies is likely to be justified. However, the new power would allow a range of matters to be prescribed in regulations, provided they are relevant to a medicine's safety, quality or efficacy. In future, for example, this could include advice on data requirements for medicines for which generic versions are more difficult to develop than for other products, e.g. those with certain types of formulations like liposomal injections which deliver a medicine within a layer of molecules to protect it from being destroyed by the immune system, or to ensure that it reaches a particular part of the body.

Item 2 – After subsection 25(2)
This item inserts new subsections (2AA) and (2AB) in section 25 of the Act.

New subsection 25(2AA) requires that if an applicant is applying for registration of a medicine and the Secretary has given advice under new section 22G in relation to the medicine, the Secretary must have regard to the advice in evaluating the medicine under section 25.

This is designed to ensure that, in addition to helping medicine sponsors be more confident about the requirements for an application, the new advice measure will also enable the advice provided by the Secretary to directly support and streamline any subsequent application for marketing approval.

New subsection 25(2AB) makes it clear that new subsection 25(2AA) does not limit the matters the Secretary may take into account in evaluating the medicine under section 25. That is, the advice is one of the matters the Secretary must have regard to in evaluating a medicine under section 25, but the Secretary may also take into account a range of other matters.

Item 3 – Before paragraph 60(1A)(aa)
This item inserts new paragraph (aaa) in subsection 60(1A) of the Act, to make clear that the advice provided by the Secretary under new section 22G is not an initial decision for the purposes of section 60 – with the effect that review and appeal rights will not be available in relation to advice provided under section 22G.

Review and appeal rights are not available in this context because the advice provided by the Secretary under new section 22G does not affect the rights of the person seeking the advice – a person who requests such advice will not be precluded from still applying for the registration of their medicine under section 23 of the Act if they are not happy with the advice provided, and the Secretary is not bound by the advice provided under new section 22G. The purpose of the advice provided under new section 22G is to assist and guide prospective section 23 applicants to better understand whether the information they hold would support a particular aspect of quality, safety or efficacy being satisfactorily established.

The applicant may or may not choose to rely on that advice, and if there are instances where the advice suggests that a sponsor's information may not be sufficient to, for example, satisfactorily establish a prescribed aspect of efficacy, the intention would be that the advice would assist the sponsor to target their efforts to compile more supporting information as suggested by the advice.

This amendment reflects that the advice is preliminary and procedural in nature, rather than a final or substantive decision that can directly affect a person's rights or interests. This would also appear to be consistent with the point made in the Administrative Review Council's publication '*What decisions should be subject to merits review?*' of 1999 (available without charge on the website of Attorney-General's Department at https://www.ag.gov.au/LegalSystem/AdministrativeLaw/Pages/practice-guides/what-decisions-should-be-subject-to-merit-review-1999.aspx), which advises that preliminary or procedural decisions are unsuitable for review as they do not have substantive consequences.

SCHEDULE 3—VARIATIONS TO APPROVED CLINICAL TRIALS

Summary
The measures in this Schedule to the Bill amend the Act to enable a sponsor of a clinical trial to request the Secretary to vary the terms of an approval for the use of unapproved therapeutic goods for use solely for experimental purposes in humans.

The Act currently enables the Secretary to approve the importation, exportation or supply of therapeutic goods that do not have marketing approval in Australia, for experimental purposes in humans, and the Secretary may also specify conditions to which such an approval is subject, e.g. that the staff participating in the trial must have suitable training to be able to recognise potential adverse events.

However, the Act does not currently allow the Secretary to vary such an approval once approval has been given. This means that if a clinical trial sponsor proposes a change to such a trial – even a minor change – they have to make a new application for a new approval. This is a long and expensive process, which may require the sponsor to re-start the trial and could delay the trial and thus access to new products in clinical trials.

The Bill addresses these concerns by amending the Act to enable a clinical trial sponsor to request the Secretary to vary the goods specified in the approval or vary the conditions imposed on the approval. Under the new measure, the Secretary will be required to make the requested variation or refuse to do so, and may approve a variation that is different to the one requested (e.g. if this is considered necessary for safety reasons). Any such decision by the Secretary will be subject to formal review and appeal rights.

Therapeutic Goods Act 1989
Item 1 – At the end of subsection 19(1)
This item makes a minor amendment to insert a note at the end of subsection 19(1) of the Act to highlight that new subsection 19(4B) (as inserted by item 3 below) provides for variations to approvals given by the Secretary under paragraph 19(1)(b) of the Act for the purpose of conducting clinical trials, i.e. for experimental purposes in humans.

Item 2 – Subparagraph 19(2)(b)(i)
Paragraph 19(2)(b) of the Act requires that an application made by a person to the Secretary under paragraph 19(1)(b) of the Act for an approval to import, export or supply unapproved therapeutic goods that are not in the Register for use solely for

experimental purposes in humans must be made in writing, accompanied by such information relating to the goods as is required by the Secretary and accompanied by the prescribed evaluation fee.

This item repeals and substitutes the first of these (in subparagraph 19(2)(b)(i) of the Act) to require that that such applications be in a form (if any) approved by the Secretary, rather than just being in writing (as currently).

This is for greater consistency with paragraph 19(2)(a) which requires applications for approval to use unapproved therapeutic goods for the treatment of another person to be on an approved form, and will also support the efficient processing of applications under section 19 of the Act.

Item 3 – After subsection 19(4A)
This item inserts new subsections 19(4B) and 19(4C) to the Act, to provide for variations to a clinical trial approval given under section 19(1)(b) of the Act.

New subsection 19(4B) provides that where the Secretary has granted an approval to a person under paragraph 19(1)(b) of the Act for import, export or supply of an unapproved therapeutic good for use in a clinical trial, and the person requests the Secretary to vary the goods specified in the approval or vary any conditions imposed on the approval by the Secretary, the Secretary must, by notice in writing, vary or refuse to vary the approval.

The effect of new subsection 19(4B) is, in particular, to permit clinical trial sponsors to request variations to the terms of their approvals without (as currently) having to go back to the start of the process and make a fresh application under paragraph 19(1)(b) of the Act, even for a minor change.

New subsection 19(4B) makes it clear that any variation made by the Secretary in response to such a request may be different to the one requested, and may involve imposing new conditions on the approval or varying or removing existing such conditions.

This might occur if, for example, a requested variation is made but there is a need for a new condition in the interests of safety, e.g. in relation to adverse event reporting.

A request under new subsection 19(4B) must be accompanied by such information required by the Secretary and the fee prescribed in the Regulations, and be in a form approved by the Secretary.

New subsection 19(4C) provides that the Secretary's notification under new subsection 19(4B) to the person who made a request to vary a clinical trials approval must set out the Secretary's decision on the request and, if the decision is to refuse the approval, or to vary the approval in a manner that is different to the requested variation, the reasons for the decision.

The effect of existing paragraph 60(1)(c) of the Act is that the full scope of any decision of the Secretary under new subsection 19(4B) will be subject to review and appeal rights.

New subsection 19(4D) makes it clear that a variation under subsection 19(4B) takes effect at the time that the Secretary notifies the person under subsection 19(4C) of the variation.

Items 4 – 9 - At the end of subsection 32CK(1), paragraph 32CK(4)(b), after subsection 32CK(9), at the end of subsection 41HB(1), paragraph 41HB(5)(a) and at the end of section 41HB
These items amend the Act to make equivalent amendments to items 1-3 above in relation to biologicals and medical devices.

Item 10 – Application provisions
This item provides that the power of the Secretary to vary a clinical trial approval under new subsections 19(4B), 32CK(9A) and 41HB(8) may be exercised in relation to approvals granted before, on or after the commencement of these provisions.

SCHEDULE 4 – PRELIMINARY ASSESSMENT OF APPLICATIONS FOR VARIATION OF PERMISSIBLE INGREDIENTS DETERMINATION

Summary
The measures in this Schedule of the Bill amend the Act to improve consistency and clarity in relation to applications to the Secretary for recommendations to amend the permissible ingredients legislative instrument made by the Minister under section 26BB of the Act (principally, these involve applications to allow the use of new ingredients in listed and assessed listed medicines).

Under the Act, all applications for marketing approval must meet specified preliminary assessment requirements, e.g. that the applicant has used the correct application form, paid the applicable application fee or (where relevant) that the application is accompanied by supporting information that is of a kind determined by the Secretary by legislative instrument. However, the Act does not set out equivalent requirements for applications for the approval of new ingredients for use in listed and listed assessed medicines.

Therapeutic Goods Act 1989
Item 1 – Subsection 3(1) (after paragraph (b) of the definition of *passed preliminary assessment*)
This item amends the definition of 'passed preliminary assessment' in subsection 3(1) of the Act, to reflect the amendments made by item 2 below to introduce a new preliminary assessment procedure for applications for new ingredients for listed and assessed listed medicines.

Item 2 – After section 26BC
This item inserts new sections 26BD and 26BDA in the Act, to set out preliminary assessment requirements that must be met for an application for a recommendation to vary the determination made by the Minister under section 26BB of the Act (in practice, these applications mainly involve proposals for the approval of new ingredients for use in listed or assessed listed medicines), and the circumstances in which such an application may lapse.

New section 26BD sets out the new requirements – principally these are that an application for a variation of the section 26BB determination must:

- be in accordance with the form approved by the Secretary for such applications;
- set out the recommendation sought;
- ensure that the prescribed application fee has been paid;
- be accompanied by supporting information that is of a kind, and in a form, determined by the Secretary in legislative instruments made under new subsections 26BD(8) and (9).

These requirements are based on the existing preliminary assessment requirements in the Act for applications for marketing approval (e.g. section 23B of the Act for registrable and assessed listed medicines).

Currently some applications of this type are not supported by sufficient information to allow the Secretary to meaningfully evaluate them and, because there is no mechanism to screen such applications at an early stage, they are often evaluated on the basis of what has been provided, and are consequently rejected.

Industry have raised concerns about this issue, and called for greater clarity around the nature and level of information needed to support a potentially successful application. These amendments are designed to address such concerns. In particular, the ability for the Secretary to make legislative instruments under new subsections 26BD(8) and (9) will make it clearer what the minimum requirements are for supporting information for new ingredient applications.

New section 26BDA provides that an application made under new subsection 26BD(1) that has passed preliminary assessment lapses in two circumstances:

- if the application contains information that is inaccurate or misleading in a material particular; or
- if information given to the Secretary in connection with the application is inaccurate or misleading in a material particular.

An application may lapse at any time when it is identified that such information is inaccurate or misleading. This is not a new mechanism. New section 26BDA is the same as the current lapsing mechanism for these kinds of applications in current subsection 26BE(2B) of the Act, which would be repealed by item 4 below. It is designed to better highlight the effect of the provision of inaccurate or misleading information in this context.

Item 3 – Section 26BE (heading)

This item repeals and replaces the heading of section 26BE of the Act to clarify that, as a result of the amendments in this Schedule, section 26BE would deal with the evaluation of an application for a recommendation to vary the section 26BB determination, as the requirements for the preliminary assessment of such applications are now outlined in new section 26BD.

Items 4 – 13 - Subsections 26BE(1) to (2B), paragraph 26BE(3), paragraph 26BE(3)(c), after subsection 26BE(3), subsection 26BE(5B) (heading), paragraphs 26BE(5B)(a) and (c), subsection 26BE(5), paragraph 26BE(5C)(b) and subsection 26BE(9)
These items principally make minor amendments to section 26BE of the Act to reflect the changes inserted by item 2 above.

Of note is item 11, which amends subsection 26BE(5B) to correct an inadvertent error in that subsection. Subsection 26BE(5B) currently requires that if an application fee is prescribed for the purposes of applications for a recommendation to vary the section 26BB determination, regulations made for the purposes of paragraph 63(2)(daaa) of the Act prescribe a period within which such applications must be made and the Secretary makes a recommendation but not within that period, then 25 per cent of the application fee must be refunded to the applicant.

Item 11 would amend the Act to replace the reference in subsection 26BE(5B) to "application fee" with a reference to "evaluation fee" to reflect the intention that, in the circumstances outlined in subsection 26BE(5B), an applicant should be entitled to a 25 per cent refund of the evaluation fee, rather than the application fee.

This reflects that the application fee relates to the cost of processing applications whereas the evaluation fee relates to the cost of assessing an applicant's proposed variation, and that the evaluation fee is the more significant of the two fees (items 28-35 of the table in Part 4 of Schedule 9 to the *Therapeutic Goods Regulations 1990* refer).

Item 14 – Paragraph 60(1A)(aa)
This item amends paragraph 60(1A)(aa) to insert a reference to section 26BD. Consistent with the other preliminary assessment provisions in the Act, a preliminary assessment under section 26BD will not, under this amendment, be an initial decision for the purposes of section 60 or 60A of the Act.

This reflects that preliminary assessment decisions are procedural in nature, and would appear to be consistent with the point made in the Administrative Review Council's publication '*What decisions should be subject to merits review?*' of 1999 (available without charge on the website of Attorney-General's Department at https://www.ag.gov.au/LegalSystem/AdministrativeLaw/Pages/practice-guides/what-decisions-should-be-subject-to-merit-review-1999.aspx). This publication advises that preliminary or procedural decisions are unsuitable for review as they do not have substantive consequences.

Item 15 – Subsection 60(2B)
This item makes a minor, consequential amendment to subsection 60(2B) to replace the reference to subsection 26BE(1) with a reference to new subsection 26BD(1), to reflect the changes made by item 2 above. The effect of the provision is unchanged, as section 60(2B) would simply refer to the new provision under which an application for a recommendation to vary the section 26BB determination is made.

Item 16 – Application, saving and transitional provisions
Paragraph (1) of this item provides that the amendments made by this Schedule only apply in relation to an application made under subsection 26BD(1) after these amendments commence. Paragraph (2) of this item provides that for applications made under the current subsection 26BE(1) of the Act, the current section 26BE and subsection 60(2B) continue to apply to such applications as in force before the amendments in this Schedule commence. Paragraph (3) of this item provides that the form approved for the purposes of paragraph 26BE(2)(a) of the Act continues in force for the purposes of paragraph 26BD(3)(a).

SCHEDULE 5 — APPROVING SUPPLY OF THERAPEUTIC GOODS UNDER AUTHORISED PRESCRIBER SCHEME

Summary
The measures in this Schedule to the Bill amend the Act to provide greater flexibility in relation to the circumstances in which medical practitioners may be authorised to supply unapproved therapeutic goods to their patients, and to reduce burden for medical practitioners and improve access to unapproved therapeutic goods for Australian consumers, particularly in remote and rural Australia.

Therapeutic Goods Act 1989
Items 1 to 3 – Subsection 19(6), subsection 32CM(4) and subsection 41HD(4)
Under the Act, the Secretary may authorise medical practitioners to supply specified unapproved therapeutic goods to their patients.

However, currently such an authority may only be given where (among other requirements) the medical practitioner has the approval of an ethics committee, except in any "exceptional circumstances" prescribed in the regulations.

These items remove the term 'exceptional' from subsections 19(6), 32CM(4) and 41HC(4) of the Act. The term 'exceptional' is ambiguous in the context of subsections 19(6), 32CM(4) and 41HC(4) and, although not intended to limit the types of circumstances that may be prescribed by the regulations, may inadvertently do so. This item removes this unintended limitation on the circumstances that may be prescribed so that circumstances where, from a public health perspective, it is not appropriate to require ethics approval may be prescribed which are arguably not 'exceptional' circumstances.

Item 4 – Application and transitional provisions
This item provides that the amendments to subsections 19(6), 32CM(4) and 41HC(4) apply in relation to an authority given on or after the commencement of this item.

This item also has the effect that regulations made for the purposes of each of these subsections that are in force immediately before the commencement of this item, are taken (on and from that commencement) to have been made for the purposes of the relevant subsection as amended by this Schedule.

SCHEDULE 6 — REMOVAL OF OFFENCES FOR PERSON CLAIMING TO BE ABLE TO ARRANGE SUPPLY OF THERAPEUTIC GOODS

Summary
The measures in this Schedule to the Bill amend the Act to remove an unintended barrier to the alleviation of shortages of therapeutic goods, including medicines.

Therapeutic Goods Act 1989
Items 1 to 3 – Subsection 22(6), subsection 32BJ(4) and subsection 41MM
The *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* introduced mandatory reporting requirements for sponsors of higher risk medicines to report shortages or decisions to permanently discontinue the supply of such products.

However, concerns have arisen that the criminal offence in subsection 22(6) of the Act may be a disincentive for sponsors of potential alternative products to a medicine affected by a shortage from identifying if they are able to arrange for the supply of their products to help alleviate the effects of the shortage.

Subsection 22(6) of the Act provides that it is an offence if a person claims, by any means, that they or another person can arrange the supply of therapeutic goods if the goods are not registered or listed in the Register or are not covered by one of the pathways in the Act for accessing unapproved goods.

Item 1 addresses these concerns by repealing the offence in subsection 22(6) of the Act, and items 2 and 3 repeal the equivalent offences in the Act for biologicals and medical devices (subsections 32BJ(4) and 41MM).

No person has ever been prosecuted for these offences, and they may provide a disincentive to addressing of issues relating to the supply of unapproved therapeutic goods during medicines shortages.

Item 4 – Saving provisions
This item provides that despite the repeal of subsections 22(6), 2BJ(4) and 41MM, these subsections continue to apply after the commencement of this Schedule in relation to claims made prior to the commencement of this Schedule.

SCHEDULE 7 — CONDITIONS OF REGISTRATION OR LISTING OF THERAPEUTIC GOODS

Summary
The measures in this Schedule to the Bill amend the Act to codify a long-standing condition of the registration or listing of therapeutic goods in the Register, to highlight that sponsors may not make changes in relation to their goods before seeking the Secretary's approval of those changes under section 9D of the Act.

Therapeutic Goods Act 1989
Item 1 – Before paragraph 28(5)(aa)
This item inserts new paragraph (aaa) in subsection 28(5) of the Act, which imposes a condition of the registration or listing of therapeutic goods that are registered or listed in the Register.

The condition requires that if:

- a person in relation to whom therapeutic goods are registered or listed in the Register proposes to make a change to the information included in the entry in the Register for their goods,; and
- the change relates to any of the matters referred to in paragraphs 25(1)(c) to (ja), 26(1)(c) to (n), 26A(2)(a) to (ja) or 26AB(2)(c) to (p) of the Act;
- the Secretary would be required, under section 9D of the Act, to vary the entry, or to consider varying the entry, if the person requested the variation under section 9D;

then it is a condition of the registration or listing of the goods that the person not make the variation unless they request the variation under section 9D and the Secretary varies the entry in accordance with that request.

This is not a new condition for sponsors of registered or listed goods. Rather it is a codification of a long-standing condition imposed by the Secretary by regulatory decision under subsection 28(2B) of the Act. It is intended to have the same effect as condition 2 in the document '*Conditions standard and specific Applying to registered or listed therapeutic goods under Section 28 of the Therapeutic Goods Act 1989*' dated July 1995/March 1998 (and available without charge at www.tga.gov.au).

This condition plays a significant role in ensuring the integrity of the Register as a current and up to date record of the terms on which registered and listed therapeutic goods are approved for supply in Australia, and in ensuring that post-market monitoring of the safety of such goods is properly informed by such information (including in relation to recalls).

Item 2 – Application provision

This item provides that the amendment in this Schedule to introduce the new statutory condition applies on and after the commencement of this Schedule.

SCHEDULE 8 — CHANGES TO PROVISIONALLY REGISTERED MEDICINE

Summary

The measures in this Schedule to the Bill amend the Act to removing an unintended barrier to access for provisionally registered medicines, and to enable sponsors of medicines which reflect certain kinds of variations to existing provisionally registered medicines (e.g. in relation to dosage form or model) to apply directly for provisional registration, without the need to first obtain a provisional determination.

Therapeutic Goods Act 1989

Item 1 - Section 23AA

This item creates a subsection for the text currently in section 23AA, to reflect the changes to be introduced by item 2 below.

Item 2 – At the end of section 23AA

This item inserts a new subsection 23AA(2) in section 23AA of the Act, which would set out a new set of circumstances in which an application under section 23 of the Act will be taken to be an application for provisional registration in the Register.

The *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* implemented R a new marketing approval pathway for promising new medicines, based on early clinical studies, to allow faster approval and availability of these products for Australian consumers. Under the new pathway (provisional registration), sponsors of new prescription medicines and new indications medicines (as defined in the regulations) are able to apply to the Secretary for a provisional determination for their medicine. This signifies that the medicine meets certain criteria, e.g. that it provides a major therapeutic advance, and must obtain such a determination to qualify to apply for a provisional registration.

As provisionally registered medicines are earlier in their life cycle than other medicines (often such medicines are the subject of ongoing clinical trials while they are provisionally registered), sponsors of these medicines may need to vary aspects of their medicines as part of their product development, while they are still provisionally registered.

However, under the current Act, a number of these kinds of variations (e.g. a different dosage form or strength) result in the creation of a separate and distinct good. This has the effect that the sponsor would have to (re)-apply for a provisional determination for each such separate and distinct good before they could apply for provisional registration.

This is an unnecessary step for sponsors, and could cause considerable delay for both sponsors and consumers in being able to access these promising new medicines for very serious conditions.

This item is designed to identify circumstances in which a sponsor may apply for the provisional registration of a medicine, without having to first obtain a provisional determination.

Principally, these circumstances are where:

- there is a medicine that is provisionally registered in the Register because of an application that, under subsection 23AA(1), was taken to be an application for provisional registration – this is the original medicine on which the new medicine is based;
- another medicine - the new medicine – is separate and distinct from the original medicine, under subsection 16(1) of the Act (this lists matters which make registrable medicines separate and distinct from one another, e.g. if they have different directions for use);
- the sponsor applies under section 23 of the Act for the registration of the new medicine, before the end of the original medicine's provisional registration period;
- the sponsor specifies in the application that they are seeking the provisional registration of the new medicine;
- at the time of that application, the active ingredients, and indications of the new medicine and the original medicine are the same.

If all these circumstances are met, the application made under section 23 of the Act in relation to the new medicine will be taken to be an application for the provisional registration of the new medicine, with no requirement for the sponsor to first obtain a provisional determination under the Act in relation to the new medicine.

Item 3 – Subparagraph 25(1)(d)(iii)
Subparagraph 25(1)(d)(iii) of the Act requires that one of the matters in relation to which the Secretary must evaluate a medicine for registration in the Register is, for a medicine for which provisional registration is sought, is that the Secretary is satisfied with the sponsor's plan to submit comprehensive clinical data on the medicine's safety and efficacy, before the end of 6 years from the day on which registration would commence.

This item amends the Act to make it clear that this requirement only applies in relation to applications for provisional registration to which subsection 23AA(1) applies – the effect of this will be that applications for provisional registration under new subsection 23AA(2) (as inserted by item 2 above) will not be subject to this requirement.

It is not considered necessary for the Secretary to consider this aspect in relation to applications involving a new medicine as provided for under new subsection 23AA(2). This is because the question of the sufficiency of the sponsor's plan to develop clinical data would have already been considered in relation to the original medicine on which such a new medicine is based.

Item 4 – Subsection 29(3)
This item repeals subsection 29(3) of the Act, and inserts new subsections (3) and (3A) in section 29.

New subsection 29(3) has the same effect as the current subsection 29(3), but makes it clear that the 2 year provisional registration period outlined in the terms of current subsection 29(3), starting from the day registration commences, applies for a medicine that is provisionally registered because of an application to which new subsection 23AA(1) applies.

New subsection 29(3A) provides that the provisional registration period for a new medicine that is provisionally registered because of an application to which new subsection 23AA(2) applies, is the period starting on the day the new medicine is registered and ending on the day the provisional registration period of the original medicine ends. Further, if the provisional registration period for the original medicine has been extended under subsection 29(6) of the Act, the provisional registration period for the new medicine ends on the day the provisional registration period for the original medicine, as extended, ends.

This item also inserts a note under new subsections 29(3) and (3A), indicating that subsection 25AB(6) of the Act provides that the registration of a medicine commences on the day specified in the certificate of registration.

Item 5 – Paragraph 29(5)(c)
This item repeals and substitutes paragraph 29(5)(c) of the Act, to set out the deadline for a sponsor of a new medicine that is provisionally registered in the Register because of an application to which new subsection 23AA(2) applies to apply for an extension of the provisional registration period for their medicine. Under the amended paragraph 29(5)(c), the current deadline will continue to apply for a sponsor of a provisionally registered medicine other than a new medicine to which new subsection

23AA(2) has applied. That is, if a person applies to extend the provisional registration period for a medicine that is provisionally registered because of an application to which subsection 23AA(1) applied, the application must be made 6 months before the provisional registration period is due to end.

However, in the case of a medicine to which new subsection 23AA(2) has applied (i.e. a medicine that is provisionally registered as a new medicine as provided for under new subsection 23AA(2)), the deadline for a sponsor of such a medicine to apply to extend the provisional registration period will be at least 1 month before the provisional registration period is otherwise due to end.

Item 6 – Subsection 29(6)
This item replaces subsection 29(6) with new paragraphs (6) and (6A), to set out what steps the Secretary must take upon receiving an application for an extension of the provisional registration period for a medicine that is provisionally registered because of an application to which new subsection 23AA(2) has applied.

New subsection 29(6), as inserted by this item, preserves the existing requirements for the Secretary in relation to an application for an extension for a provisionally registered medicine other than one to which new subsection 23AA(2) applies. Under these, the Secretary must decide to grant or refuse to grant the application, and must have regard to whether the Secretary is satisfied with the sponsor's plan to submit comprehensive clinical data on the medicine's safety and quality before the end of 6 years from when provisional registration commenced.

New subsection 29(6A) applies in relation to a medicine that is provisionally registered because of an application to which new subsection 23AA(2) has applied. The Secretary must also decide to grant or refuse to grant an application for an extension for such a medicine, but is not required to have regard to whether the Secretary is satisfied with the sponsor's plan to submit comprehensive clinical data on the medicine's safety and quality, as that requirement will not apply to provisionally registered medicines that were the subject of an application to which subsection 23AA(2) has applied (item 3 above refers).

Item 7 – Subsection 29(7)
This item makes a minor amendment to subsection 29(7) of the Act to reflect the effect of item 6 above.

Item 8 – Subsection 29(8)
This item makes a minor amendment to subsection 29(8) of the Act to add a specific reference to applications "in relation to a medicine", to better highlight the existing requirement under subsection 29(8) that no more than 2 extensions may be granted for a provisionally registered medicine for applications under subsection 29(4).

Item 9 – After subsection 29(8) (after the note)
This item amends the Act to insert new subsection (8A) in section 29 of the Act. New subsection 29(8A) makes it clear that the Secretary must not extend the provisional registration period for a new medicine to which new subsection 23AA(2) has applied so that the period would end more than 6 years after the provisional registration of the original medicine (on which it is based) commenced. That is, the provisional

registration period for the new medicine must not be extended beyond the provisional registration period for the original medicine.

For example, if the original medicine's provisional registration period commenced on 1 January 2022 and the new medicine's provisional registration period commenced on 1 January 2023, the new medicine's provisional registration period could not be extended beyond 1 January 2028 (i.e. 6 years after the original medicine's provisional registration period commenced).

Note that this does not affect the Secretary's separate power to extend a period of provisional registration for a medicine under subsection 29(9) of the Act, if the medicine's sponsor has submitted an application for the full registration of the medicine and the extension is for the purposes of the Secretary's obligation to under paragraph 29(10)(b) of the Act to ensure that the provisional registration period continues while the Secretary evaluates the application for full registration.

Item 10 – Paragraph 60(2D)(a)
This item amends paragraph 60(2D)(a) of the Act to include a reference to new subsection 29(6A). The effect of this amendment is to only allow the person in relation to whom a medicine is provisionally registered to seek review under section 60 of a decision made under new subsection 29(6A) in relation to an application for an extension of the period of provisional registration for a medicine that is provisionally registered because of an application to which new subsection 23AA(2) has applied.

Item 11 – Application and saving provisions
This item provides that new paragraph 23AA(2)(a) applies in relation to a medicine provisionally registered before, on or after the commencement of this item. New paragraph 23AA(2)(d) applies in relation to an application made on or after the commencement of this item. New subparagraph 25(1)(d)(iii) applies in relation to an application for provisional registration of a medicine that is made on or after the commencement of this item.

New subsections 29(3) and (3A) apply in relation to an application for provisional registration of a medicine that is made on or after the commencement of this item. New paragraph 29(5)(c) applies in relation to an application made under subsection 29(4) of the Act on or after commencement. The repeal of subsection 29(6) does not affect the validity of a decision made under that subsection before the commencement of this item.

SCHEDULE 9 — DATA PROTECTION FOR CERTAIN LISTED MEDICINES

Summary
The measures in this Schedule to the Bill amend the Act to introduce a data protection regime in relation to assessed listed medicines (these are listed medicines that are listed in the Register but that are assessed by the Secretary in relation to their claims for efficacy before they are given marketing approval). This supports the implementation of Expert Panel Review recommendation 50, which was accepted by government in 2016, and asked that improved competitiveness of the Australian

complementary medicines industry be explored, by providing incentives for innovation.

The new regime provides a period of five years' protection for clinical trial information that a sponsor of an assessed listed medicine submits in support of an indication (these are statements about a product's therapeutic use), where the information is not available to the public and where there was no other medicine in the Register with that indication when the assessed listed medicine was included in the Register.

Therapeutic Goods Act 1989

Item 1 – Subsection 3(1)

This item introduces a new placeholder definition for 'restricted information' in section 3(1) of the Act which refers to the meaning given by new section 26AF, which is introduced by this Schedule.

Item 2 – At the end of subsection 26AE(1)

This item introduces a note at the end of subsection 26AE(1) to highlight that, under new section 26BF (to be introduced by item 3 below) the Secretary must not use restricted information when evaluating the medicine under section 26AE for listing in the ARTG.

Item 3 – After section 26AE

This item introduces new section 26AF to the Act after section 26AE. New section 26AF introduces a new data protection scheme in relation to assessed listed medicines (these are medicines that are listed in the Register under section 26AE of the Act), which is similar to the existing data protection regime for registered medicines in section 25A of the Act.

New subsection 26AF(1) provides that if an application is made under section 23 of the Act for listing of a medicine under section 26AE, in evaluating the medicine under section 26AE, the Secretary must not use information about other medicines that is restricted information. That is, the Secretary is prohibited from using restricted information, as defined by new subsection 26AF(2), when evaluating a medicine under section 26AE.

The effect of this is to preclude sponsors of other, "generic" assessed listable medicines from relying on such restricted information to support an application for the listing of their own medicines under section 26AE of the Act.

The criteria for information to be 'restricted information' in this context are set out in new subsection 26AF(2). These are that the information is:

- the information was given to the Secretary in relation to an application made under section 23 of the Act for the listing of a medicine under section 26AE of the Act (i.e. the new data protection regime will only apply in relation to listed assessed medicines, and not in relation to other listed medicines);
- the information is derived from a clinical trial that relates to an indication of the medicine (and where the indication is not a permissible indication covered by a determination made by the Minister under paragraph 26BF(1)(b) of the Act);
- the information is not available to the public;

- at the time the application to list the medicine in the Register under section 26AE of the Act was made, there was no other medicine with the same indication in the Register, and no other medicine with the same indication had been included in the Register at any time before then;
- the medicine is listed in the Register under section 26AE of the Act;
- five years have not passed since the commencement of the medicine's listing in the Register (i.e. this is the period for which a listed medicine sponsor's restricted information will be protected under the new data protection regime); and
- the sponsor of the medicine has not given the Secretary their permission in writing for the Secretary to use the information (i.e. in connection with another medicine application).

Information will only be 'restricted information' for the purposes of the new data protection regime where all of these criteria are met.

The provision enables five years' protection for clinical trial information that a sponsor submits in support of an indication for an assessed listed medicine, where the criteria outlined above apply.

This will ensure that if a sponsor of a generic version of the same medicine were to apply for marketing approval during that five-year period, they would not be able to rely on the protected information in relation to the evaluation of their product. This measure support is designed to provide a significant incentive for assessed listed medicine sponsors to undertake and invest in research to improve the efficacy of their products.

This measure is designed to provide incentive for the complementary medicines sector to innovate and invest in research to improve the efficacy of their products.

Item 4 – After subsection 30(4A)
This item inserts new subsection (4B) in section 30 of the Act, which deals with the cancellation of registered and listed therapeutic goods from the Register.

New subsection 30(4B) requires that the Secretary must cancel the entry of an assessed listed medicine from the Register if the Secretary becomes aware that restricted information was used when evaluating the medicine for listing – i.e. contrary to the prohibition inserted by new subsection 26AF(1).

This is consistent with, and based on, the existing requirement in subsection 30(4A) of the Act that the Secretary must cancel the registration of therapeutic goods if the Secretary becomes aware that information that is protected under the existing data protection regime for registered medicines was used in the goods' evaluation – i.e. contrary to the prohibition in subsection 25A(1) of the Act.

This reflects that there may be instances where, during evaluation, the Secretary may not be aware that some information is restricted information.

Item 5 – Subsection 61(8)
Subsection 61(8) of the Act provides that, subject to the existing data protection regime for registered medicines in section 25A of the Act, therapeutic goods

information (as defined in subsection 61(1) of the Act) may be used by the Department in the consideration of another matter that relates to therapeutic goods, or may be given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods.

This item amends subsection 61(8) to make it clear that the these uses and disclosures are subject to both the existing data protection regime for registered medicines in section 25A of the Act, and the new data protection regime for assessed listed medicines in new section 26AF.

Item 6 – Application provisions
This item provides for the application of new subsections 26AF(1) and 30(4B). New subsection 26AF(1) applies in relation to an application made on or after the commencement of this item. New subsection 30(4B) applies in relation to a medicine listed on or after the commencement of this item where the application for listing was made on or after that commencement. That is, it only applies to medicines listed following a future application for listing.

SCHEDULE 10 — OTHER AMENDMENTS

Summary
The measures in this Schedule to the Bill include a number of more minor amendments to the Act, including in particular to:

- remove spent and redundant references in the Act to therapeutic devices to reflect that this is a superseded category of therapeutic goods, and remove a small number of other spent and redundant provisions;
- amend a small number of headings to make it clear that the provisions to which they relate set out approvals or authorities in relation to the supply of unapproved therapeutic goods, rather than exemptions;
- clarify the Secretary's power to specify classes of registrable or assessed listable therapeutic goods for the purposes of the preliminary assessment requirements for applications for marketing approval for such products; and
- include a reference to the *Agreement on Mutual Recognition in Relating to Conformity Assessment, Certificates and Markings between the Government of the United Kingdom of Great Britain and Northern Ireland (the UK) and the Government of Australia* in the definition of 'therapeutic goods information' in subsection 61(1) of the Act, to ensure that the Secretary will be able to disclose information relating to the performance of the Department's functions under that Agreement once it enters into force.

Patents Act 1990
Item 1 – Subparagraph 119A(1)(a)(ii)
This item amends subparagraph 119A(1)(a)(ii) of the *Patents Act 1990* (the Patents Act), to remove the reference in that subparagraph to therapeutic devices. This amendment is consequential to the amendments in this Schedule (outlined below) that remove references to therapeutic devices from the Act.

These measures, and this amendment to the Patents Act, reflect that therapeutic devices are a superseded product category following the introduction of Chapter 4 to the Act by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* (the 2002

Amendment Act). Chapter 4 regulates as medical devices products that, before the 2002 Amendment Act, were registered or listed in the Register under Part 3-2 of the Act, alongside medicines.

Products that were formerly therapeutic devices are now all medical devices and are regulated under the regulatory scheme for medical devices. Accordingly, the reference to therapeutic devices is redundant.

Therapeutic Goods Act 1989

Item 2 – Subsection 3(1)

This item inserts a definition for the Australia-UK Mutual Recognition Agreement in subsection 3(1) of the Act. The new definition refers to the Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates And Markings between the Government of Australia and the Government of the United Kingdom of Great Britain and Northern Ireland, as in force from time to time. This agreement was entered into in 2019 and can be accessed (without charge) in the Australian Treaties Series on the AustLII website: http://www.austlii.edu.au/au/other/dfat/treaties/

Items 3 - 16, 19 - 21, 25 - 37, 39 - 41 and 45 – Removal of references to therapeutic devices, and related amendments

These items amend the Act to repeal spent and redundant references to therapeutic devices, and to make related consequential amendments, to reflect that 'therapeutic devices' is a superseded product category following the introduction of Chapter 4 to the Act by the 2002 Amendment Act and the transitioning of products that were, before the 2002 Amendment Act, regulated under Part 3-2 of the Act to regulation as medical devices under Chapter 4 of the Act.

In particular, the amendments made by these items include changes to:

- repeal the definition of 'therapeutic device' from subsection 3(1) of the Act;
- amend the definition of 'medicine' in subsection 3(1) of the Act, to remove the reference to goods that are declared not to be therapeutic devices;
- repeal and substitute section 15A of the Act (which currently provides for circumstances in which Part 3-2 of the Act may apply to a medical device) with a new section 15A that makes it clear that Part 3-2 does not apply to medical devices;
- repeal and substitute section 33A of the Act (which currently provides that Part 3-3 of the Act does not apply to a medical device unless Part 3-2 of the Act applies to the device, with a new section 33A that makes it clear that Part 3-3 does not apply to medical devices; and
- repeal the note under the heading to Chapter 4 of the Act, and section 41BJ of the Act, to reflect that medical devices are not regulated under Part 3-2 of the Act.

Item 17 – Section 19 (heading)

Subsection 19(1) of the Act enables the Secretary to, by notice in writing, grant an approval to a person for the importation into, exportation from, or supply in, Australia, of specified unapproved therapeutic goods for use in the treatment of another person or for use solely for experimental purposes in humans.

Subsection 19(5) of the Act enables the Secretary to authorise a specified medical practitioner to supply specified therapeutic goods for use in the treatment of humans,

or a specified class of such goods, to the class or classes of recipients specified in the authority.

Subsection 19(7A) of the Act enables the Minister to, by legislative instrument, make rules authorising any health practitioner who is included in a class of such practitioners specified in such an instrument to supply specified therapeutic goods for use in the treatment of humans, or a specified class of such goods, to the class or classes of recipients specified in the instrument.

However, while these mechanisms are identified as approvals or authorisations, the heading of section 19 of the Act refers to "Exemptions for certain uses".

This item repeals and replaces the heading of section 19 of the Act, to refer to approvals or authorities rather than exemptions.

Item 18 – Section 19A (heading)
This item makes a similar amendment to repeal and replace the heading of section 19A of the Act. Section 19A provides that the Secretary may, by notice in writing, grant an approval to a person for the importation into, or the supply in, Australia of specified therapeutic goods if the Secretary is satisfied of specified matters including in particular that registered goods that could act as a substitute for the goods are unavailable or in short supply.

The current heading of section 19A refers to exemptions. This item repeals and replaces the heading of section 19A of the Act to refer to approvals where there is an unavailability of goods, rather than exemptions.

Item 22 – Section 23A
This item makes a minor amendment to section 23A to accommodate the amendment made by item 23 below.

Item 23 – At the end of section 23A
Section 23A of the Act provides that the Secretary may, by notifiable instrument, specify different classes of therapeutic goods for the purposes of section 23B of the Act.
Section 23B of the Act sets out the preliminary assessment requirements that an application for registration or an application for the listing of a medicine as an assessed listed medicine must meet before proceeding to evaluation (e.g. that the correct application form must be used for each class of such goods).

This item inserts new subsection (2) in section 23A of the Act, to provides that a class of therapeutic goods that the Secretary may specify under section 23A may be specified by reference to one or more of the matters referred to in paragraphs 16(1)(a) to (g) or 16(1A)(a) to (d).

The purpose of this amendment is to clarify that the Secretary may specify classes of therapeutic goods for the purposes of section 23B of the Act by reference to any of the characteristics listed in subsections 16(1) and (2). For example, the Secretary could specify classes of therapeutic goods for the purpose of section 23B by reference to different indications, different dosage forms or different pack sizes.

Item 24 – Transitional provision
This item provides that an instrument in force under section 23A of the Act at the time this item commences continues in force on and after this item commences, as if it were made under new subsection 23A(1) of the Act. That is, any instrument made under section 23A of the Act would continue to be in force after the amendments to 23A made by this Schedule.

Item 38 – Section 32CM (heading)
This item repeals and replaces the heading to section 32CM of the Act, consistent with the amendments made by items 17 and 18. The current heading describes section 32CM as providing exemptions for health practitioners to supply biologicals. However, it would be more correctly referred to as an authority, under the terms of the section 32CM. The new heading refers to authorities for health practitioners instead of exemptions for health practitioners.

Item 42 – Section 41HC (heading)
This item repeals and replaces the heading to section 41HC of the Act, consistent with the amendments made by items 17, 18 and 38. The current heading describes section 41HC as providing exemptions for health practitioners to supply medical devices. However, it would be more correctly referred to as an authority, under the terms of section 41HC. The new heading refers to authorities for health practitioners instead of exemptions for health practitioners.

Item 43 – Paragraph 46A(4)(b)
This item amends paragraph 46A(4)(b) of the Act to replace the current reference to registration or listing of therapeutic goods in that paragraph with a reference to registration, listing or inclusion. This is for consistency and to reflect that biologicals and medical devices are 'included' in the Register whereas medicines (or other therapeutic goods) are registered or listed in the Register.

This measure is also designed to ensure that the powers of an authorised person to search premises for the purposes of finding out if the Act or the regulations are being complied with includes premises to which a sponsor is required to provide access to as a condition of inclusion of a biological or a kind of medical device in the Register, and in so doing to support the post-market monitoring of therapeutic goods.

Item 44 – Section 52EB
This item repeals section 52EB of the Act as this is a redundant provision. Section 52EB deals with compensation for the acquisition of property resulting from the operation of section 52EA. Section 52EA was repealed from the Act in 2015 by the *Acts and Instruments (Framework Reform)(Consequential Provisions) Act 2015*, so section 52EA no longer has application.

Item 46 – Subsection 60(1) (paragraph (c) of the definition of *initial decision*)
This item amends paragraph (c) of the definition of 'initial decision' in subsection 60(1) of the Act to clarify that recommendations made under paragraph 26BE(4)(a) or subsection 26BJ(8) of the Act are not initial decisions for the purposes of section 60.

A recommendation under paragraph 26BE(4)(a) is a recommendation to vary a determination made by the Minister under section 26BB of the Act (such

determinations list ingredients that are permitted for use in listed and assessed listed medicines) in the manner requested by an applicant. A recommendation under subsection 26BJ(8) of the Act is a recommendation to vary a determination made under section 26BF of the Act (such determinations list indications that are permitted for use in relation to listed and assessed listed medicines (though assessed listed medicines may also have other indications)) in the manner requested by an applicant.

The effect of this amendment is principally to preclude third parties from seeking the review and appeal of recommendations by the Secretary in relation to the variation of these determinations. Where the Secretary makes the recommendation sought by an applicant under section 26BE or 26BJ, it is not expected that the applicant would seek review of such a recommendation, as it would align with their request, and would be favourable to the applicant.

The preclusion of such rights for third parties is principally designed to reflect the comments made by the Panel in making Review recommendation 47. Review recommendation 47 recommended the introduction of review and appeal rights for persons applying for the approval of new ingredients for use in listed and assessed listed medicines. However, the Panel noted that the existing appeal rights mechanism in section 60 of the Act would not be appropriate for new ingredients because the range of interested parties could potentially extend to a large number of people, which could create significant uncertainty in the predictability of the application process. The Panel noted that this could be overcome if review and appeal rights for new ingredient applications were restricted to the person making the application.

Amendments were made to the Act by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (the 2017 Amendment Act) to introduce review and appeal rights to implement recommendation 47. In so doing, the 2017 Amendment Act provided that such rights were, in the event of a refusal by the Secretary to recommend a new ingredient, limited to the person making the application.

However, the 2017 Amendment Act inadvertently omitted measures to reflect the Panel's concerns about review and appeal rights for third parties in relation to positive decisions by the Secretary to recommend a new ingredient as requested by an applicant (as opposed to the situation for a refusal), and the potential effects of such rights on the ingredients process.

Accordingly the Bill makes the amendment to paragraph 60(1)(c) of the Act outlined above, and for consistency and to address similar issues, also makes the same amendment for recommendations requested by applicants for variations to the permitted indications determination for such products.

Item 47 – Application provision
This item provides that the amendment to paragraph (c) of the definition of 'initial decision' in subsection 60(1) of the Act applies to decisions made on or after the commencement of this item.

Item 48 – Paragraph 60(2AB)(c)
This item repeals paragraph 60(2AB)(c) of the Act, which refers to the making of a decision under section 23B of the Act in relation to an application for provisional

registration of a medicine and provides that only the applicant can seek review under section 60 of the Act. This is inconsistent with the terms of paragraph 60(1A)(aaa) of the Act, which makes it clear that a preliminary assessment under section 23B is not an initial decision. Accordingly, this item repeals paragraph 60(2AB)(c), to address this inconsistency.

Item 49 – Subsection 61(1) (definition of *therapeutic goods information*)
Section 61 of the Act sets out a range of circumstances in which the Secretary may release therapeutic goods information, including by legislative instrument.

'Therapeutic goods information' is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and that relates to the performance of the Department's functions, including functions relating to the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community (the EU MRA), as in force from time to time, and the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Free Trade Association, as in force from time to time.

In January 2019, Australia and the United Kingdom (the UK) signed the Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates and Markings between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of Australia (the UK MRA) which, broadly, continues the operation of the EU MRA as between Australia and the UK, once the UK is no longer covered by the EU-MRA.

Under article 10 of the UK MRA, that Agreement takes effect on the later of the date on which the EU MRA ceases to apply to the UK or when both Parties have confirmed the completion of their internal procedures relating to the Agreement (Australia has already done this).

This item makes a minor amendment to the definition of therapeutic goods information in subsection 61(1) of the Act to include a reference to the UK MRA alongside the existing reference to the EU MRA, to ensure that the Secretary will be able to disclose information relating to the performance of the Department's functions under the UK MRA, once that Agreement takes effect.