EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022

The Regulations introduce a priority pathway for promising new biologicals, and support continuity of access to medical devices for Australian patients.

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia. Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022* (the Regulations) amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to introduce a priority pathway for the accelerated evaluation of applications for the inclusion of promising new biologicals (such as, potentially, genetically modified cell therapies for treating cancers) in the Australian Register of Therapeutic Goods (the Register).

The Regulations also ensure continuity of access to medical devices in Australia by:

- extending transitional arrangements for in vitro diagnostic (IVD) medical devices that are companion diagnostics (IVD companion diagnostics), from 1 July 2022 to 26 May 2026. These are pathology tests for identifying the presence or absence of biological features, such as genes, to determine whether a person is likely to benefit or be at risk from a particular medicine or biological. This aligns with similar arrangements in the European Union (EU); and
- reducing fees for requests for consent to import or supply medical devices that do not comply with Australian labelling requirements as a result of transitioning to complying with new legislation in the EU.

The first of these measures is needed because similar transitional arrangements for IVD companion diagnostics were recently extended in the EU until May 2026. There is a risk that if the transitional arrangements in the MD Regulations are not aligned with the EU, this may lead manufacturers and sponsors to avoid the Australian market, impacting patients. The timing of this measure (rather than before 30 June 2022) was affected by the timing of the 2022 Federal election.

The second of these measures is needed because large numbers of manufacturers and sponsors of medical devices are currently impacted by a transition in the EU from one set of regulations to a new set of regulations (the vast majority of medical devices in Australia are imported, and many rely on EU evidence that they comply with minimum safety and performance criteria). As a result of transitioning to the new EU regulations, many devices may inadvertently contravene Australian regulatory requirements. The Act provides a mechanism for sponsors to avoid penalties for such contraventions through applying for the Secretary's consent to import and supply their devices in such circumstances. As it is expected that there will be a large volume of such applications, and as a model to manage

them efficiently has been developed, a reduced fee is being introduced to reflect those efficiencies and reduce burden for affected sponsors.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

Schedule 1 to the Regulations commences retrospectively on 1 July 2022. This ensures that existing transitional arrangements which commenced on 1 February 2020 and ended on 30 June 2022, may continue until 26 May 2026 without a gap that would expose IVD companion diagnostics to the new regulatory framework. The effect of the retrospective commencement is wholly beneficial to those affected by the transitional arrangements (sponsors and manufacturers of IVD companion diagnostics), enabling sponsors to continue to lawfully supply these products without uncertainty or delay, and ensuring uninterrupted access to these critical products for Australian patients. The retrospective commencement is not expected to adversely affect rights or impose liabilities, and as such is not inconsistent with subsection 12(2) of the *Legislation Act 2003*.

Schedules 2 and 3 to the Regulations commences on the day after registration on the Federal Register of Legislation.

Consultation

Public consultation was conducted on the proposed introduction of a priority pathway for biologicals from 28 February 2022 to 28 March 2022. All 25 respondents (including industry organisations and peak bodies, state regulators, health professional organisations, consumer groups and individuals) were supportive of the proposal. In June 2022, Regulatory and Technical Consultative Forum (RegTech) members (including the Medical Technology Association of Australia) were consulted on the proposed medical device fee reduction, and supported the proposal. In relation to the extension of the transitional arrangements for IVD companion diagnostics, RegTech members initiated feedback on this matter during the first half of 2022, rather than the TGA initiating a consultation. The Regulations reflect the changes that RegTech members requested as part of their feedback and concerns.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022*.

Section 2 – Commencement

This section provides for Schedules 2 and 3 to the Regulations to commence the day after registration on the Federal Register of Legislation, and for Schedule 1 to commence retrospectively on 1 July 2022.

Subsection 12(1A) of the *Legislation Act 2003* provides that, despite any principle or rule of common law, a legislative instrument or notifiable instrument may provide that the instrument, or a provision of the instrument, commences before the instrument is registered. Subsection 12(2) of the *Legislation Act 2003* relevantly provides that the instrument or provision does not apply in relation to a person to the extent that, as a result of the commencement, a person's rights as at the time the instrument is registered would be affected so as to disadvantage the person, or liabilities would be imposed on the person in respect of anything done or omitted to be done before the instrument is registered (under subsection 12(4) of the *Legislation Act 2003*, the effect of subsections 12(1A) or (2) in relation to an instrument is subject to any contrary provision in an Act).

The retrospective commencement relates to the amendments in Schedule 1 to the Regulations, which are designed to extend the end date of transitional arrangements relating to the introduction of the new regulatory framework for IVD companion diagnostics. This was introduced by the *Therapeutic Goods Legislation (2019 Measures No. 1) Regulations 2019* (the 2019 Amendments) on 1 February 2020, to align with an extension of similar transitional arrangements for such products in the EU. The existing transitional arrangements ended on 30 June 2022 and these arrangements are to continue through retrospective commencement of the Schedule 1 amendments. This approach ensures that IVD companion diagnostics are not subject to the new regulatory framework for a short period from 1 July 2022 until the Regulations are made. The retrospective commencement of this amendment is wholly beneficial to those affected. It enables sponsors to continue supply of these devices and give sponsors more time to comply with the new regulatory framework. It also benefits patients by ensuring uninterrupted supply of these critical products. The retrospective commencement is therefore necessary and not expected to adversely affect rights or impose liabilities.

There is no contrary intention to the application of subsections 12(1A) and (2) of the *Legislation Act 2003*.

Section 3 – Authority

The Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

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

Schedule 1 – Extension of transitional period for IVD companion diagnostics

The *Therapeutic Goods Legislation (2019 Measures No. 1) Regulations 2019* (the 2019 Amendments) amended the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to introduce a new regulatory framework for in vitro diagnostic (IVD) medical devices that are IVD companion diagnostics (Schedule 4 to the 2019 Amendments refers). The new framework included, in particular, clarifying that IVD companion diagnostics are classified as Class 3 IVD medical devices or Class 3 in-house IVD medical devices, and that they would be subject to identification using a unique product identifier (UPI). The UPI for a IVD companion diagnostic is a characteristic that identifies if such a medical device is taken to be of the same kind as another device or not.

The 2019 Amendments included transitional arrangements for IVD companion diagnostics, set out in regulation 11.54 of the MD Regulations, for IVD companion diagnostics mentioned in subregulations 11.54(3), (4) or (5). The transitional period ended on 30 June 2022.

This amendment extends the transitional period to 26 May 2026 to align with the new (extended) transitional arrangements for IVD companion diagnostics in the *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* (EU IVD Regulation). The significant impact of COVID-19 on the diagnostics industry has resulted in delays in the uptake and full implementation of the EU IVD Regulation in Europe, prompting the European Parliament to extend the transitional arrangements initially set out under the EU IVD Regulation through amending legislation. The effect of these amendments is that existing Class C IVD medical devices (equivalent to Class 3 IVDs in Australia, and therefore applicable to IVD companion diagnostics) which have been lawfully supplied in the market in Europe now have until 26 May 2026 to comply with the EU IVD Regulation requirements.

It is considered that a similar extension in Australia is necessary to allow manufacturers and sponsors time to meet the equivalent requirements introduced under the IVD companion diagnostics framework in Australia, so as not to precede the EU changes and therefore ensure the uninterrupted supply of these IVD medical devices in Australia.

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Subregulations 11.54(2) and (6)

This item amends subregulations 11.54(2) and (6) to omit the words “1 July 2022” and substitute “26 May 2026”.

Schedule 2 – Fee for application for consent of Secretary

Section 41FD of the Act sets out a number of matters in relation to which an applicant for the inclusion of a kind of medical device in the Australian Register of Therapeutic Goods (the Register) must certify. Relevantly, paragraph 41FD(f) provides that an applicant must certify that appropriate conformity assessment procedures have been applied to devices of that kind, or requirements comparable to such procedures have been applied to medical devices of that kind.

The conformity assessment procedures are specified in the MD Regulations and set out the requirements relating to the application of quality management systems in the manufacture of medical devices, and other requirements relating to obligations of manufacturers of medical devices.

Section 41FDA of the Act requires that, when certifying the matter referred to in paragraph 41FD(f), the applicant must also state whether the certification is based on a conformity assessment certificate (issued by the Secretary), an Australian conformity assessment body certificate or an overseas regulator conformity assessment document.

An 'overseas regulator conformity assessment document' is a certificate or other document that is issued by an overseas regulator after that regulator is satisfied that requirements, comparable to the conformity assessment procedures, have been applied to a medical device by the manufacturer. The comparable overseas regulators have been specified in the *Therapeutic Goods (Overseas Regulators) Determination 2018* (the Overseas Regulators Determination), which is a notifiable instrument made under section 41BIB of the Act and is freely available from the Federal Register of Legislation at www.legislation.gov.au.

Under the Overseas Regulators Determination, an overseas regulator includes a body that has been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices (a notified body).

The regulation of medical devices in Europe is currently undergoing a transition to the new *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* and the new *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* (EU Regulations), which replace the following directives ("EU Directives"):

- *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities;
- *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* of the Council of the European Communities;
- *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*.

Most medical devices are included in the Register based on a conformity assessment document issued by a notified body under the EU Directives, supporting certification under paragraph 41FD(f) of the Act. These medical devices will be required to transition to the new EU Regulations to continue to be able to be supplied in Australia (EU transition). Transition

to the EU Regulations has introduced a range of changes for manufacturers of medical devices including, for example:

- more stringent requirements to demonstrate medical device safety for patients and users, including requirements for clinical evidence;
- additional requirements for the quality management systems of manufacturers;
- detailed technical document requirements;
- changes to classification rules for some medical devices.

As a result of the EU transition, many sponsors and manufacturers will be required to obtain alternative conformity assessment documentation to support the inclusion of their devices in the Register and enable continued supply of the devices in Australia. Under subparagraph 41FN(3)(b)(i) of the Act, it is a condition of inclusion that the sponsor has available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of medical device or that requirements, comparable to those procedures, have been applied to the kind of medical device to the satisfaction of an overseas regulator.

Issues arising for some manufacturers and sponsors in relation to the transition include delays in having an overseas regulator conformity assessment document issued by a notified body under the EU Regulations, or changes to products included in the Register as a result of the new requirements under the EU Regulations.

To help minimise regulatory burden, cost and impact on supply, a risk-based and streamlined approach that does not compromise safety, quality or performance of medical devices supplied in Australia is being adopted by the TGA in relation to managing the transition of medical devices to the EU Regulations from a regulatory perspective, including ensuring that patients and health professionals in Australia are kept up to date about any changes affecting medical devices that are in use in Australia.

As part of this approach, the TGA is expecting to receive a large number of requests for a consent to import, supply or export a transitioning medical device that does not comply with the labelling requirements in Essential Principle 13 (Clause 13 of Schedule 1 to the MD Regulations).

The TGA intends to streamline the assessment of such applications, by adapting the approval process to ensure applications are processed in a timely manner and potentially granting a consent on receipt of an appropriate implementation plan that clearly outlines how the sponsor will ensure that regulatory requirements in Essential Principle 13 will be met.

The amendments in this Schedule have the effect of supporting these efforts by reducing the fee for a request to the Secretary for consent to import or supply a medical device that does not comply with Essential Principle 13 for transitioning medical devices that are non-compliant as a result of the transition of the device to the EU Regulations. A reduced fee of $30 will apply in such circumstances to requests made from 1 January 2022 and a refund will be made where the higher fee has already been paid prior to the commencement of these amendments.

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Division 9.1A (heading)

This item amends the heading of Division 9.1A to omit "patient implant cards and patient information leaflets" and substitute "information requirements".

Item [2] – Paragraph 9.1AA(1)(b)

This item repeals and replaces paragraph 9.1AA(1)(b) to include a reference to the application of clause 13 of Schedule 1 to the MD Regulations (Essential Principle 13) where non-compliance with clause 13 is because the medical device is affected by the EU transition. The effect of this amendment is that the reduced fee provided in subregulation 9.1AA(1) also applies where a medical device that is transitioning in the EU to compliance with the EU Regulations is non-compliant with Essential Principle 13. The reduced fee applies where both subparagraphs 9.1AA(1)(b)(i) and (ii) apply.

Item [3] – Paragraph 9.1AA(2)(b)

This item repeals and replaces paragraph 9.1AA(2)(b) to include a reference to the application of clause 13 of Schedule 1 to the MD Regulations (Essential Principle 13) where non-compliance with clause 13 is because the medical device is affected by the EU transition. The effect of this amendment is that the reduced fee provided in subregulation 9.1AA(2) also applies where a medical device that is transitioning in the EU to compliance with the EU Regulations is non-compliant with Essential Principle 13. The reduced fee applies where both subparagraphs 9.1AA(2)(b)(i) and (ii) apply.

Item [4] – At the end of regulation 9.1AA

This item introduces subregulation 9.1AA(3) which sets out when a medical device is affected by the EU transition. New subregulation 9.1AA(3) provides that a medical device that is affected by the EU transition is one that is included in the Register on the basis of certification of the matter in paragraph 41FD(f) in reliance on a certificate issued under the EU Directives, as in force from time to time, and certification has been (or will be) issued under the EU Regulations, as in force from time to time.

The new subsection incorporates by reference the following documents:

- *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities, which sets out the requirements for active implantable medical devices available in the EU;
- *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* of the Council of the European Communities, which sets out the requirements for medical devices available in the EU;
- *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, which sets out the requirements for in vitro medical devices available in the EU;

- *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,*; and
- *Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices*.

These documents have been incorporated as in force from time to time in accordance with section 63(4) of the Act (which provides a contrary intention to the application of section 14 of the Legislation Act). These documents are freely available from EUR-Lex at https://eur-lex.europa.eu/.

Item [5] – In the appropriate position in Part 11

This item introduces Division 11.15 in Part 11 of the MD Regulations. New regulation 11.68 provides a mechanism for refunding the difference in the fee under item 1.15 of Schedule 5 to the MD Regulations and the reduced fee in regulation 9.1AA. The refund would only be made where an application for a consent to non-compliance with Essential Principle 13 for transitioning medical devices was made after 1 January 2022 and before the commencement of these amendments, and the fee in item 1.15 of Schedule 5 was paid.

Schedule 3 – Biological (priority applicant) determinations

In November 2017, the Act was amended to include a provision allowing the regulations to provide for and in relation to the priority review of biologicals (section 32DEA of the Act refers). However, changes were not made to the *Therapeutic Goods Regulations 1990* (the TG Regulations) at that time to implement the priority pathway.

The effect of these amendments introducing the priority pathway for biologicals is to support earlier access for patients to certain new biologicals which may have significant advantages over existing treatments, or which may provide a treatment option where there are no existing treatments, for life-threatening or seriously debilitating conditions.

These amendments empower the Secretary to make biologicals (priority applicant) determinations and related arrangements and, where such a determination is made, assessment of the application for marketing approval for the particular product will be fast-tracked by the TGA while continuing to be subject to all quality, safety and efficacy requirements under the Act. The expedited review process will be undertaken on a full set of supporting information without truncation of the assessment processes.

Review and appeal rights will apply in relation to decisions to refuse to make a biologicals (priority applicant) determination and decisions to revoke such determinations.

Therapeutic Goods Regulations 1990

Item [1] – Section 2

This item adds a definition of 'biologicals (priority applicant) determination' for the purposes of the amendments in this Schedule, with that term having the meaning given by subsection 32DEA(2) of the Act.

Item [2] – After Part 3C

This item introduces a new Part 3D to the TG Regulations, which makes provision for and in relation to the making of a biologicals (priority applicant) determination for the purposes of subsection 32DEA(2) of the Act.

New regulation 16U makes it clear that new Part 3D applies in relation to the making of a biologicals (priority applicant) determination for biologicals.

New regulation 16V sets out the requirements for persons applying to the Secretary for a biologicals (priority applicant) determination – principally, these are that the application must be in accordance with the relevant form approved by the Secretary, and must be accompanied by sufficient supporting information to allow the Secretary to properly consider the application. If these steps are not met, or if the prescribed application fee has not been paid, the application will be taken not to have been made.

New subregulation 16W(1) provides that, on receiving an application for a biologicals (priority applicant) determination that is in accordance with regulation 16V, the Secretary must consider the application and decide either to make the determination or refuse to do so.

New subregulation 16W(2) sets out the criteria for qualifying for a biologicals (priority applicant) determination, and enables the Secretary to make such a determination if satisfied that:

- the biological is separate and distinct from biologicals included in the Register;
- either the intended clinical use of a Class 2 biological, or the therapeutic indication of a Class 3 or 4 biological, (the priority indication) is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
- either there are no therapeutic goods intended to treat, prevent or diagnose that condition already in the Register or, if there are, there is substantial evidence showing that the biological provides a significant improvement in terms of efficacy or safety (or both) compared to those other goods; and
- there is substantial evidence showing that the medicine provides a major therapeutic advance – generally considered an improvement in the safety and/or efficacy of a therapeutic good that is well above the minimum threshold of clinical significance, and the evidence to support this must be substantial.

New regulation 16W(3) provides that, where the Secretary makes a biologicals (priority applicant) determination, the determination must set out the name of the priority applicant, the active ingredients of the biological to which the determination relates and the priority indication. The Secretary must also notify the applicant in writing as soon as practicable after making a decision and, in the case of a refusal, provide reasons. Review rights apply for sponsors whose applications are refused.

New regulation 16X provides that a biologicals (priority applicant) determination comes into force on the day the Secretary notifies the applicant of the decision to make the determination, and will remain in force for 6 months. If an applicant makes an application under section 32DD of the Act to include the biological in the Register that passes preliminary assessment before the end of that 6-month period, the determination remains in force until either of the following occurs:

- the priority applicant withdraws the application;
- the application lapses in accordance with section 32DH; or
- the application is finally determined, i.e. when the Secretary decides to include the biological in the Register, or where the Secretary decides not to include the biological in the Register and there is no longer any possibility of a change in the outcome of that decision.

Where a sponsor has not applied for inclusion of the biological in the Register within 6 months of the determination coming into force, the determination will remain in force until the end of that 6 month period. This is to avoid delays and to support the efficient processing of biologicals for which such determinations are made, so they can be available for patients as soon as possible.

New section 16Y sets out the instances in which the Secretary may revoke a biologicals (priority applicant) determination – principally where:

- either the applicant has not yet applied to include the biological in the Register, or has done so but that application has not passed preliminary assessment; and
- the Secretary is satisfied that the criteria for a biologicals (priority applicant) determination are no longer satisfied in relation to the biological.

Items [3] to [5] – Subregulation 48(1) (definition of eligible person, table items 2 and 3, at the end of column 1, and definition of initial decision, after paragraph (ed))

These items amend regulation 48 to make it clear that a decision of the Secretary to refuse to make a biologicals (priority applicant) determination, and a decision to revoke a biologicals (priority applicant) determination, is subject to review and appeal rights for the unsuccessful applicant.

Item [6] – Part 2 of Schedule 9A (after table item 2)

This item introduces an application fee for applicants applying for a biologicals (priority applicant) determination, in the amount of $13,971. This amount principally reflects the additional expected Departmental staff effort involved in relation to these applications, including that it is expected that the TGA will hold meetings with applicants to assist them to understand the process and requirements.

Item [7] – Part 2 of Schedule 9A (table items 4 to 6)

This item amends Part 2 of Schedule 9A to prescribe evaluation fees for applications for inclusion of Class 2, 3 and 4 biologicals in the Register. The table of fees in Part 2 of Schedule 9A, at table items 4 to 6, includes a range of evaluation fees relating to applications to include a biological in the Register. Items 4 to 6 will be replaced to specify higher evaluation fees that will apply for applications to include a biological in the Register that is covered by a biologicals (priority applicant) determination that is in force. This is to reflect the additional expected Departmental staff effort involved in evaluating these applications for biologicals that are the subject of a biologicals (priority applicant) determination.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022* (the Regulations) are 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 Legislative Instrument
The Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The purpose of the *Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to introduce a priority pathway for the accelerated evaluation of applications for the inclusion of promising new biologicals (such as, potentially, genetically modified cell therapies for treating cancers) in the Australian Register of Therapeutic Goods (the Register).

The Regulations also ensure continuity of access to medical devices in Australia by:

- extending transitional arrangements for in vitro diagnostic (IVD) medical devices that are companion diagnostics (IVD companion diagnostics), from 1 July 2022 to 26 May 2026. These are pathology tests for identifying the presence or absence of biological features, such as genes, to determine whether a person is likely to benefit, or be at risk, from a particular medicine or biological. This aligns with similar arrangements in the European Union (EU); and
- reducing fees for requests for consent to import or supply medical devices that do not comply with Australian labelling requirements as a result of transitioning to complying with new legislation in the EU.

The first of these measures is needed because similar transitional arrangements for IVD companion diagnostics were recently extended in the EU until May 2026. There is a risk that if the transitional arrangements in the MD Regulations are not aligned with the EU, this may lead manufacturers and sponsors to avoid the Australian market, impacting patients. The timing of this measure (rather than before 30 June 2022) was affected by the timing of the 2022 Federal election.

The second of these measures is needed because large numbers of manufacturers and sponsors of medical devices are currently impacted by a transition in the EU from one set of regulations to a new set of regulations (the vast majority of medical devices in Australia are imported, and many rely on EU evidence that they comply with minimum safety and performance criteria). As a result of transitioning to the new EU regulations, many devices may inadvertently contravene Australian regulatory requirements. The Act provides a mechanism for sponsors to avoid penalties for such contraventions through applying for the Secretary's consent to import and supply their devices in such circumstances. As it is expected that there will be a large volume of such applications, and as a model to manage

them efficiently has been developed, a reduced fee is being introduced to reflect those efficiencies and reduce burden for affected sponsors.

Human rights implications

The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

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 the 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 Regulations take positive steps to support the right to health by:

- supporting the timely availability of biologicals that represent a new, advanced treatment option for Australian patients;
- enabling the continued supply of IVD companion diagnostic in Australia through the alignment of transitional periods in Australia with the EU; and
- facilitating the continued supply in Australia of medical devices that are transitioning to compliance with new regulations in the EU and that may not immediately meet all Australian regulatory requirements.

Conclusion

The Regulations are compatible with human rights because they maintain and support the right to health in Article 12 of the ICESCR as outlined above, and do not raise any other human rights issues.

Mark Butler, Minister for Health and Aged Care