



Australian Government

Department of Health

Department of Health response to the Productivity Commission Issues Paper: Right to Repair

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Introduction

The Department of Health, through the Therapeutic Goods Administration (TGA), regulates the supply, import, export, manufacturing and advertising of therapeutic goods to ensure that therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

The therapeutic goods regulatory framework also requires that therapeutic goods continue to be safe and fit for use throughout the product lifecycle. Compliance functions support the broader regulatory objectives, including consumer protection, and enabling a fair market for industry. The Department monitors, and enforces where necessary, compliance with the legislation, regulations and rules for therapeutic goods; import, manufacture, advertising, supply, and export. The Australian therapeutic goods regulatory framework is closely aligned with those of comparable international regulatory counterparts wherever possible.

In addition to being regulated under the [Therapeutic Goods Act 1989](#) and associated regulations, therapeutic goods, including medical devices, may also be subject to other regulatory requirements, including Australian consumer law. This submission is being provided because medical devices may be subject to repair, and so changes to rights to repair may apply to these products. The comments provided in this submission are limited to issues relevant to the regulation of medical devices as therapeutic goods. As a result, this submission does not address various information requests raised by the Issues Paper, where they relate to issues beyond the scope of the therapeutic goods regulatory framework (see Attachment A for any specific comments against information requests).

Background

What is a medical device

Medical devices are the therapeutic good category likely to have associated repair requirements. Medical devices are instruments, apparatus, appliances, software, implants, reagents, materials or other articles intended for human therapeutic use. Broadly, for medical devices therapeutic use means:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, alleviation or compensation for a disease, ailment, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- control or support of conception
- in vitro examination of a specimen derived from the human body for a specific medical purpose

Regulatory framework

The *Therapeutic Goods Act 1989*, the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#), and a number of Orders and Determinations, set out the legal requirements for the import, export, manufacture, supply and advertising of medical devices in Australia.

Medical devices are classified based on risk, based on their intended purpose.¹ The higher the classification level of a device, the higher the requirements for the conformity assessment procedures that manufacturers must apply to their device (explained further below).

Medical devices must be included in the Australian Register of Therapeutic (ARTG) before they can be lawfully supplied in, imported into, or exported from Australia (unless exempt from being entered in the ARTG, or otherwise authorised by the TGA.). For a medical device to be included in the ARTG, the applicant or '[sponsor](#)' provides satisfactory evidence that:

- the medical device complies with the essential principles
- demonstrate that the appropriate conformity assessment procedure has been applied

Essential principles

The essential principles set out the fundamental design and manufacturing requirements for medical devices.² There are six general Essential Principles that apply to all therapeutic medical devices (relating to health and safety, including long-term safety, with benefits outweighing the risks), and a further nine Essential Principles about design and construction that apply to devices on a case-by-case basis (including principle 15 which applies only to *in vitro* diagnostic (or IVD) medical devices).

This principles-based regulatory framework caters for technological diversity and advances and changes in the development of new medical devices, and provides flexibility for manufacturers. The framework does not mandate the means by which a manufacturer must prove that they have met the essential principles, but this is most readily established by complying with international standards, where these are applicable.

The use of a medical device is never entirely without risk. The essential principles require that design and construction of medical devices seeks to eliminate or reduce risks as far as possible.³ Residual risks associated with the use of a medical device must be acceptable when weighed against the intended benefit for the patient.⁴

Conformity assessment

Conformity assessment is the systematic and ongoing examination **by the manufacturer** of evidence and procedures to determine that the safety of a medical device is acceptable and the device performs as intended and, therefore, conforms to the essential principles.

The applicant must be able to demonstrate that the appropriate conformity assessment procedure has been applied to the device in order to apply for inclusion of the medical device in the ARTG. For all but the lowest risk medical devices this is demonstrated by providing certification issued to the manufacturer by an appropriate assessment body (which may be the TGA or a comparable overseas

¹ For *in vitro* diagnostic (or IVD) medical devices, classification is also based on the public health risk or personal risk that may arise from an incorrect result.

² The essential principles are prescribed in [Schedule 1 of the Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

³ [Essential principle 2](#) - Design and construction of medical devices to conform with safety principles

⁴ [Essential principle 1](#) - Use of medical devices not to compromise health and safety

regulator). The higher the classification level of a device, the higher the requirements for the conformity assessment procedures that manufacturers must apply to their device, and the more rigorous the oversight when seeking certification of the conformity assessment procedure.

Risk management plan: As part of their conformity assessment procedure, the manufacturer of a medical device will have a risk management plan, documenting the risks for the medical device, the mitigations applied to those risks, and any residual risks for the device. Although for many devices the TGA does not directly certify the conformity assessment procedure (ie this has been done by a comparable overseas regulator), the risk management plan, together with the clinical evaluation report, are the key documents. These are requested in application audits (which may be undertaken for any application to include a device in the ARTG, and are mandatory for high risk devices using certification from comparable overseas regulators) or post market investigations of a medical device. These documents can be requested by at any time, and the Australian sponsor must have arrangements in place with the manufacturer to provide these document to the regulator within 20 working days.

Regulation across the medical device life cycle

Once a device is included in the ARTG, manufacturers are required to continue monitoring the performance and safety of their devices and ensure continued compliance with the essential principles. This surveillance program is part of the quality management system aspect of their conformity assessment procedure, and will be periodically checked by the certifying body (whether this is the TGA or a comparable overseas regulator), appropriate to the intended purpose and risks of the device.

Data generated from safety and adverse event reports and complaints, newly identified risks, literature, any updated or new clinical investigations, significant regulatory actions and formal surveillance activities such as registries are used by the manufacturer to review the performance, safety and benefit-risk assessment of the device, and update risk management arrangements as appropriate.

The sponsor also has ongoing obligations, including reporting on adverse incidents, overseas regulatory actions, and the results of investigations undertaken by the manufacturer, such as further clinical studies and reviews of adverse events.

Post-market monitoring is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market, including investigation of medical device adverse event and complaints, imposing and monitoring various reporting requirements, periodic inspections of manufacturers' quality management systems and technical documentation, and checking evidence of conformity against the essential principle.

Issues

Medical devices as consumer goods

As noted above, medical devices may also be consumer products, and so changes around a 'right to repair' would flow through to many medical devices. However it should be noted that not all medical devices are not necessarily consumer products.

- **Equipment used in health practice** is often used by health professionals rather than consumers. These products vary widely, from expensive equipment such as MRI scanners, to inexpensive consumables such as gloves and masks. It is noted that some of these may attract consumer protections where used for business purposes, and the increase of the threshold from \$40,000 to \$100,000 (from July 2021) will expand the application of consumer law to a broader range of such medical devices.
- Some medical devices, while the patient is the end user, are nevertheless not easily characterised as consumer products, where product selection and use is **facilitated by medical practitioners**. Examples include implantable medical devices such as hip or knee replacements, pacemakers, etc. There are particular issues related to repair of implanted medical devices (discussed below)
- The Issues Paper notes a focus on *physical* products for the purposes of the consultation, given the difficulty in 'repairing' intangible goods or service, and discusses **software** in particular. It should be noted that many medical devices may include software, and software can be a medical device in itself (including software supplied separately to a medical device, or stand-alone software such as apps).
- Some medical devices in use in Australia may not be included in the ARTG and therefore are **unapproved**.
 - For some of these devices health professionals are involved and manage some of the risk ([custom made medical devices](#), and unapproved products supplied under the [Special Access Scheme](#) or [Authorised Prescriber Scheme](#)). It is not clear whether these would be considered consumer goods, as they are not freely available.
 - Individuals may import many unapproved medical devices for [personal use](#). Even where the product is identical to a product which is approved (ie included the ARTG) the Australian sponsor has no obligation, at least under the therapeutic goods framework, to support the product sourced as a personal import (including warranties or repairs).

Repair of medical devices

Repairs to medical devices may be required if goods are faulty in any respect or if they are damaged. In some cases maintenance of the medical device might include a service schedule, the supply of spare parts or other regular maintenance such as adjustments (eg hearing aids).

Sponsors, as the applicant to include the medical device in the ARTG, are responsible for the ongoing safety and efficacy of their medical devices (including liaison with the manufacturer). In practice, repairs may be undertaken by the manufacturer or their agents (perhaps but not necessarily

including the Australian sponsor), medical device repair companies or other interested parties including health professionals (eg dental technicians).

Manufacturers are responsible for the design and production of a medical device, whether located in Australia or overseas. As outlined above, the manufacturer, in complying with the essential principles, may limit, restrict or prohibit the repair of the medical device to mitigate health and safety risks. Medical devices, even those which appear to be simple or low risk, can be dangerous when not working as intended, given the nature of the technology and vulnerability of intended users.

Manufacturers may seek to restrict the use and possibly repair of a medical device in a wide range of ways. As a minimum, medical devices are provided with Instructions for Use⁵ which include detail on the use of the device, and associated risks and warnings, which may include instruction on whether and how to repair the device. Further restriction may be achieved much as for other consumer products, including physical barriers (tamper proof casing etc), warranty restrictions, use of internal software, intellectual property restrictions, licensing arrangements, etc. The higher the risks associated with the product (taking into account the product itself, the users and patients it is intended for, expected operational environment, etc) the more robust the management of risk is required to be (including any risks associated with repair).

Repairers using spare parts not specified by the manufacturer may be subject to legal liability risk if the unapproved spare part causes the medical device to fail and users of the repaired device may be subject to risks to their health. This liability may be under the modification and refurbishment requirements discussed below, or under other causes of action.

It should all be noted that an accessory to the medical device is also, in itself, a medical device. Repairers of medical devices sourcing accessories from third party suppliers are required to ensure that the accessories already have TGA approval to ensure that is legal to supply that item in Australia for use with the medical equipment. Where accessories are sourced from overseas the repairer will become the sponsor of the accessory (or would need to find someone will to be the sponsor) and subject to the responsibilities of sponsors of therapeutic goods.

Revision

In addition general repair requirements and restrictions, some medical devices have particular issues around 'revision'. This primarily applies to implantable medical devices, and it is unclear whether these would be considered consumer products.

There are particular concerns around the quality, safety and performance of implantable medical devices. In many cases these replace anatomy (such as joint replacements) or are critical to sustaining life (such as pace makers). These devices are often intended for long term use; for example a hip, knee or shoulder joint replacement may have a 15 year anticipated life span. The repair or replacement of such medical devices is a significant clinical event for the patient. The time span for these issues can be significant for these medical devices - where a device was implanted towards

⁵ [Essential principle 13.4](#) requires Instructions for Use be provided for all devices, unless the device is lower risk and can be used safely for its intended purpose without instructions

the end of the commercial life cycle of the product, revision might be sought 30 or more years after the medical device was first approved, with the end limit being the human lifespan.

This becomes an issue where 'spare parts' may be required down the track, often for devices which are no longer commercially available (superseded models, replaced by new technologies, etc). 'Repair', or revision of the existing device by replacing worn parts, may be clinically preferable as being less invasive than fully replacing the medical device. This is not specifically dealt with under therapeutic goods regulatory framework, although many medical device manufacturers maintain stocks of 'spare parts' for such devices for significant time periods after they cease commercial supply. It is not anticipated that this would be dealt with by any 'right to repair' provisions, but is raised here to illustrate some of the peculiarities associated with the repair of medical devices.

Modification and refurbishment

Where a medical device is modified or significantly refurbished the repairer may be considered to be a new manufacturer for the medical device, and subject to the obligations of manufacturers. Any modification which changes the intended purpose for the device, or refurbishment beyond the scope provided for in the original manufacturer's Instructions for Use, may trigger this change in manufacturer. This would require a new ARTG inclusion, based on a new assessment against the essential principles, including the application of appropriate conformity assessment (including certification by TGA or a comparable overseas regulator).

In practice, many repairers will be unable to satisfy these regulatory requirements, having insufficient information about the original design and construction of device (which the original manufacturer is under no obligation to provide). Even when modification or refurbishment is undertaken by the original manufacturer any substantial changes to the design, production or intended performance of the device will require assessment.

This aspect of the medical devices regulatory framework will provide a practical limit to any right to repair provisions, and is a necessary element of regulating the safety, quality and performance of medical devices.

Reuse and reprocessing of medical devices

Medical devices are assessed and included in the ARTG based on the manufacturer's intended purpose. It is the responsibility of the manufacturer to determine whether a device should only be for single use or single patient use. If the device is only intended to be for single use this must be clearly stated on the device, the label or the Instructions for Use.⁶

Any reprocessing facility is regulated as the manufacturer of the reprocessed device, and is required to demonstrate that the reprocessed device is equivalent to the original and will continue to perform without additional risk to the patient. When a single use device (SUD) is reused or reprocessed, the TGA considers that the device has been remanufactured as the:

⁶ [Essential principle 13 – Information to be provided with medical devices](#)

- intended purpose and design specifications for the device are altered from single use to reusable
- the device may undergo manufacturing processes, such as sterilisation, repackaging, relabelling, etc
- the device may need to have components replaced so that it can be reused
- the original manufacturer can no longer be considered responsible for the safety and performance of the device.

While reuse and reprocessing of medical devices is permitted, in practice it is quite difficult for the new manufacturer to comply with regulatory requirements. They must provide evidence that the material used in the original manufacture of the device can withstand repeated reprocessing, the design of the device allows for adequate cleaning and sterilisation, and that the device can continue to perform as intended. The new manufacturer must ensure that the technical documentation addresses the following issues that are relevant to the remanufacturing process, that:

- the materials used to make the original device and the biocompatibility of those materials is not affected
- the cleaning and disinfection processes are validated as effective, including appropriate viral inactivation studies
- prion, including transmissible spongiform encephalopathy, hazards are suitably mitigated and controlled
- the sterilisation processes have been validated to demonstrate the achievement of a suitable sterility assurance level
- endotoxins do not exceed the allowable limit for medical devices
- the device will continue to perform as originally intended without additional risk to the patient or end user.

Personalised medical devices

As outlined briefly above, the medical devices regulatory framework provides that custom-made medical devices were exempt from the requirement to be included in the ARTG. The TGA is currently implementing changes to narrow this provision, and introducing new regulatory requirements for patient matched medical devices, medical device production systems, adaptable medical devices and diagnostic images and anatomical models.

The new framework which commences from 25 February 2021, with transitional arrangements through to 2024. Detailed guidance is available on the TGA website.⁷ It is not anticipated that these changes will directly impact any 'right to repair' changes beyond the issues outlined above, but if further information is required please contact the TGA.

⁷ www.tga.gov.au/resource/personalised-medical-devices-including-3d-printed-devices

Software as a medical device

Software is also an emerging issue for the regulation of medical devices, and some changes are occurring for their regulation. These changes will also commenced from 25 February 2021, and guidance is available on the TGA website.⁸ It is not anticipated that these changes will directly impact any 'right to repair' changes beyond the issues outlined above, but if further information is required please contact the TGA.

Recommendation

As noted in the Commission's approach to the inquiry, this consultation is seeking to identify unnecessary barriers to repair. Based on the particular regulatory requirements for medical devices in addition to normal consumer protections, restrictions to repair to manage health and safety concerns would be deemed necessary. Whether an exemption to 'right to repair' provisions for health and safety issues would be needed will depend on the manner in which the 'right to repair' provisions are designed and implemented.

Given the broad potential overlap between medical devices covered by therapeutic goods regulation and Australian Consumer Law, it would not be appropriate to simply exempt or exclude medical devices from the operation of Australian Consumer Law. Patients and health professionals are consumers of these products and the ongoing protection of their rights, including any emerging repair rights, is important.

There is no scope to build a 'pre-assessment' of the interaction of medical device regulation and Australian Consumer Law into the assessment of individual medical devices, given:

- **Volume:** There were nearly 7,000 applications for new ARTG entries for medical devices in 2019-20⁹.
- **Expertise:** The TGA does not have the relevant expertise on Australian Consumer Law
- **Opportunity:** For the majority of medical devices approval is based on conformity assessment certification by comparable overseas regulators, limiting opportunity to assess mitigations of health and safety risks for individual medical devices, which may interact with right to repair provisions.

Depending on the construction of any 'right to repair' provisions, an exemption might be required to allow for manufacturers and sponsors to assert a health and safety rationale for non-compliance with right to repair provisions. In practice they may need to explain (and potentially provide evidence of) why any restrictions were necessary to mitigate health and/or safety risks associated with their medical device/s.

⁸ www.tga.gov.au/regulation-software-based-medical-devices

⁹ Therapeutic Goods Administration, *Annual performance statistics report 2019-20*, available on the TGA website at www.tga.gov.au/resource/annual-performance-statistics-report-july-2019-june-2020. Note that the application numbers were significantly higher than average in 2019-20 due to COVID-19, but there were more than 4,000 applications in 2018-19, with numbers building year on year.

It is not clear from the Issues Paper whether health and safety exceptions are already in place around the interaction of therapeutic goods regulation and Australian Consumer Law. The Department of Health is willing to assist in reviewing any 'right to repair' provisions or mechanisms to ensure compatibility with the therapeutic goods regulatory framework.

Department of Health responses to information requests

Right to Repair – Productivity Commission Issues Paper

INFORMATION REQUEST 1

What would a ‘right to repair’ entail in an Australian context? How should it be defined?

The Department of Health does not have a policy position on how a ‘right to repair’ should be defined. However if such ‘right to repair’ requirement is introduced, it should provide for the management of health and safety requirements for medical devices.

INFORMATION REQUEST 2

- a) What types of products and repair markets should the Commission focus on?*
- b) Are there common characteristics that these products share (such as embedded technology and software or a high/low degree of product durability), and which characteristics would allow policy issues to be considered more broadly?*
- c) If there are particular products that the Commission should focus on, what are the unique issues in those product repair markets that support such a focus?*

As outlined in this submission, there is overlap between medical devices regulated under the therapeutic goods regulatory framework and consumer products. There are a range of issues which falls under the banner of ‘repair’ which may need to be considered.

INFORMATION REQUEST 3

- a) Do the consumer guarantees under the ACL provide adequate access to repair remedies for defective goods? If not, what changes could be made to improve access to repair remedies? Are there barriers to repairing products purchased using new forms of payment technologies, such as ‘buy now pay later’?*
- b) Is the guarantee of available repair facilities and spare parts effective in providing access to repair services and parts? Or is the opt-out clause being widely used, making the guarantee ineffective?*
- c) Should consumer guarantees seek to balance the broader societal costs of remedy choices (such as the environmental impacts of replacements) with consumer rights, and if so how? For example, should repairs be favoured as a remedy?*
- d) Are consumers sufficiently aware of the remedies that are available to them, including the option to repair faulty products, under the ACL’s consumer guarantees?*
 - If not, would more information and education be a cost-effective measure to assist consumers understand and enforce guarantees? What would be the best way to deliver this information? What other measures would be more effective?*

Adverse events reported include instances of medical devices not performing as intended (including breaking) and the Department of Health investigates these events from a user health and safety perspective. The Department of Health does not hold supply information to allow comment on existing or potential access to repair remedies for medical devices as consumer products.

INFORMATION REQUEST 4

- a) *The Commission is seeking information on the nature of repair markets in Australia, including detailed data on the repair markets for specific products, covering:*
- *market size — by employment, revenue, number of businesses, profit margins*
 - *market composition — such as market share between authorised, independent and DIY repairers.*
- b) *Is there any evidence of a difference in quality, safety or data security between authorised repair networks and independent repairers? Are there ways to address concerns around quality, safety or data security while promoting a vibrant independent repair market?*
- c) *Are there available examples of the contracts between OEMs and authorised repairers? Do these contracts limit effective competition in repair markets (such as by limiting the number and reach of authorised repairers or requiring authorised repairers to not be authorised by a competing brand)?*
- *What is the process to become authorised? Is it open and competitive?*
- d) *Are there specific examples or other evidence of practices by OEMs or their authorised repairers that create barriers to competition in repair markets?*
- *Do other factors also create barriers to competition in repair markets, such as short-sighted consumer behaviours, switching costs, poor information availability or consumer lock-in?*
- e) *What is the relationship between the intensity of competition in the primary product market and the risk of consumer harm from a lack of competition in repair markets? Can competitive primary markets compensate for non-competitive repair markets?*
- *Is an absence of effective competition in the primary market a necessary condition for consumer harm from non-competitive repair markets?*
 - *To what extent would measures that enhance competition in the primary market address concerns about a lack of competition in repair markets?*
- f) *Are the restrictive trade practices provisions of the CCA (such as the provisions on misuse of market power, exclusive dealing or anti-competitive contracts) sufficient to deal with any anti-competitive behaviours in repair markets?*
- g) *What policy changes could be introduced if there is a need to increase competition in repair markets and improve consumer access to, and affordability of, repairs?*
- *What are the costs and benefits of any such proposal to the community as a whole? How does it balance the rights of manufacturers and suppliers, with those of consumers and repairers?*

The therapeutic goods regulatory framework regulates the import, export and supply of medical devices, but largely not the repair of medical devices. As outlined in this submission, in some cases

repair of a medical device may effectively make the ‘repairer’ the manufacturer of a new medical device, which would be regulated independently from the initial device. In practice this would be unusual, and is not tracked, so no data on this can be provided.

INFORMATION REQUEST 5

- a) *To what extent do current IP laws already facilitate repairs by consumers or independent third parties (e.g. the spare parts defence under the Design Act)?***
- b) *Are there any aspects of IP laws where consumers’ rights with respect to repairs are uncertain?***
- c) *Do current IP protections (e.g. intellectual property rights, technological protection measures, end-user licencing agreements) pose a significant barrier to repair in Australia? If yes, please comment on any or all of the following:***
 - *the specific IP protections that prevent consumers from sourcing competitive repairs and/or inhibit competition in repair markets***
 - *the types of products or repair markets these barriers mainly affect***
 - *the prevalence of these barriers***
 - *the impacts of these barriers on third party repairers and consumers (e.g. financial cost, poorer quality repairs)***
 - *options for reducing these barriers and their associated benefits, costs and risks (including potential impact on market offerings).***
- d) *In what ways might government facilitate legal access to embedded software in consumer and other goods for the purpose of repairs? What are the pros and cons of these approaches?***

In terms of regulating medical devices themselves, intellectual property protections are only relevant to the therapeutic goods regulatory framework insofar as it is used to manage risk associated with the device and its user/s. It is noted that use of intellectual property protections to manage health and safety risks associated with a medical device (such as using proprietary software to prevent modification of a device) may also have the effect of restricting repair.

INFORMATION REQUEST 6

- a) *What evidence is there of planned obsolescence in Australian product markets? Do concerns about planned obsolescence principally relate to premature failure of devices or in them being discarded still working when more attractive products enter the market?***
- b) *How can the Commission distinguish between planned product obsolescence and the natural evolution of products due to technological change and consumer demand?***
- c) *How does planned obsolescence affect repairers, consumers and the broader community in Australia?***
- d) *What measures do governments currently use to prevent planned obsolescence or mitigate its effects (in Australia and overseas)? How effective are these measures?***
- e) *What are the benefits, costs and risks of Australia adopting measures similar to those currently used overseas, such as product design standards and reparability ratings?***

- f) Do consumers have access to good information about durability and reparability when making purchases? If not, how could access to information be improved?**

Planned obsolescence issues may intersect with medical device regulation, as the lifespan of a medical device can be clinically relevant to the treatment of the patient. The anticipated device life span must be fit for purpose in relation to the intended purpose of the medical device. Devices intended for long term use should have suitable lifespan or be readily replaceable. Beyond that, consideration of issues associated with planned obsolescence, such as costs to consumers and environmental impacts, is beyond the scope of the Department of Health's medical device regulatory remit.

INFORMATION REQUEST 7

- a) What data are available on the amount of e-waste generated in Australia?**
- **What data is there on the composition of e-waste in terms of particular materials (such as hazardous materials) by product type?**
 - **How does hazardous e-waste compare to hazardous general waste in its prevalence and risks? Is there merit in distinguishing between hazardous e-waste and non-hazardous e-waste? And if so, how could this be done in practice?**
- b) What estimates are available on the costs of e-waste disposal on the environment, human health and social amenity, in Australia and internationally?**
- **How do the impacts differ by disposal type, or by the type of product or hazardous material?**
- c) How much of Australia's e-waste is shipped overseas for recycling? Is there evidence of circumstances where this creates problems for recipient countries?**
- **Are there barriers to the expansion of domestic recycling facilities or the adoption of new recycling technologies in Australia (such as plasma arc incinerators)?**
- d) What are Australia's current policy settings for managing the potential environmental and health effects of e-waste (such as landfill bans, the National Television and Computer Recycling Scheme or Mobile Muster)? Are these policy settings broadly right — that is, are they proportional to the impacts of e-waste on the community?**
- e) How can a right to repair policy further reduce the net costs of e-waste in Australia, and would such an approach be an effective and efficient means of addressing the costs of e-waste to the community?**

Consideration of e-waste is beyond the scope of the Department of Health's medical device regulatory remit, except where this relates to disposal requirements for a particular medical device (eg biological or medical waste recommendations, radiation protection, etc). This does not preclude the application of requirements for medical devices under other regulatory frameworks (such as current work to implement the [Minimata Convention on Mercury](#)).

INFORMATION REQUEST 8

- a) What policy reforms or suite of policies (if any) are necessary to facilitate a 'right to repair' in Australia?**
- b) Are there any other barriers to repair and/or policy responses that the Commission should consider?**

- c) What are the costs and the benefits of the various policy responses that have been proposed to facilitate repair (such as those outlined in table 1)?***
- d) Are there other international policy measures or proposals that the Commission should consider as part of this inquiry?***

The Department of Health is supportive of the rights of patients, as consumers, being maintained for medical devices which are also consumer products, subject to allowance for health and safety requirements.