Australian Government
Department of Health
Therapeutic Goods Administration

Report on TGA processes and timeframes for the regulation of medical devices and access to market

International benchmarking

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TGA Health Safety Regulation

Contents

Executive summary

Recommendation 21 of the Review of Medicines and Medical Devices Regulation (MMDR Review) suggested that the Therapeutic Goods Administration (TGA) establish target timeframes that reflect international benchmarks and the typical lifecycle of a medical device for the conduct of conformity assessments.

mpconsulting was engaged to undertake consultation within the TGA and with comparable overseas bodies to determine how international bodies regulate medical devices and examine how the TGA's process and timeframes compare with international regulators.

All of the countries consulted are members of the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators working together towards harmonisation in relation to requirements for the safety, performance, and quality of medical devices. As such, while there are some differences in each country's approach to regulating medical devices, there is a level of comparability. For example, each country:

- has adopted legislation that specifically outlines the essential requirements a medical device must meet to be sold within that country
- classifies medical devices based on their level of risk
- uses a risk-based approach to regulate medical devices to ensure the level of regulation matches the risks posed by the device.

However, for the purpose of understanding the processes and timeframes for pre-market authorisation, there remain quite significant differences across countries that make it difficult to directly compare these processes and timeframes. For example:

- Australia is the only country to separate out the pre-market approval and market authorisation steps
  - In Australia, pre-market assessment of a medical device (i.e. conformity assessment undertaken by the TGA or a third-party conformity assessment body) is a distinct step that occurs prior to market authorisation of the device (i.e. inclusion on the Australian Therapeutic Goods Register (ARTG)).
  - In other countries, once a medical device has been assessed as meeting conformity assessment requirements, it is automatically approved for sale within that country.
  - The different approach in Australia reflects that more than 90% of applications for inclusion on the ARTG use overseas conformity assessment authorisation.
- some countries separate review of the manufacturer's quality management systems from product design examination
  - For example, in Brazil and Canada, a manufacturer must have their QMS certification prior to applying for conformity assessment of the device; whereas in Australia, these occur in parallel as a part of TGA's conformity assessment for high risk devices.
- each country measures their performance in a different way.
  - Australia calculates timeframes based on 'TGA business days' (i.e. the clock is stopped when awaiting a response from the applicant) and timeframes are based on the date of paid application submission to the date a decision is made. Others use business days or calendar days and timeframes may be based on when they first respond to (or request further information from) the applicant.

- Australia does not aggregate assessment timeframes based on the class/risk/complexity of the device. Other countries such as Brazil, Singapore and the United States differentiate assessment timeframes based on the class of device, such that higher risk devices have longer assessment timeframes.

Table 1 summarises our findings regarding approval timeframes across the countries consulted (noting differences in the way target timeframes are calculated for different classes).

Acknowledging the differences in approach and performance measurement noted above, the TGA's timeframes for pre-market approval of high-risk devices are broadly comparable with international benchmarks (and in a number of cases, more efficient).

The approach to medical device regulation in the EU (i.e. for the United Kingdom (UK) and the Netherlands) most closely aligns with that of Australia. Target timeframes are also most closely aligned in these countries, noting that actual timeframes are not available as conformity assessment is undertaken by private, commercial bodies (known as Notified Bodies) in the UK and the Netherlands and are not required to publish this information.

The TGA is the only regulator that allows applicants to use comparable overseas conformity assessment authorisation to support market entry for all but the most high-risk classes of devices. This further reduces the timeframes and administrative burden associated with bringing medical devices to market in Australia, in line with the different levels of complexity and risk posed by different device classes.

The TGA is currently undergoing a range of reforms stemming from the MMDR Review that are expected to further streamline timeframes for pre-market approval (i.e. TGA conformity assessment) of medical devices.

Table 1: Comparison of international approaches and timeframes for pre-market approval of medical devices, including IVD medical devices

	Australia		UK		Netherlands		Brazil		Singapore		Japan	USA	Canada
Regulator name	TGA		MHRA		Ministry of Health, Welfare and Sports		Anvisa		HSA		PMDA	FDA	Health Canada
Device classification	*Medical devices* I IIa IIb III AIMD	*IVDs* 1 2 3 4	*Medical devices* I IIa IIb III	*IVDs* List A List B	*Medical devices* I IIa IIb III	*IVDs* List A List B	*Medical devices* I II III IV	*IVDs* I II III IV	*Medical devices* A B C D	*IVDs* A B C D	I II III IV	I II III	I II III IV
	All countries classify devices by risk (lowest to highest). Key difference between regulators is that some explicitly split IVDs and medical devices and others treat together.												
Low risk devices	**Class I and 1:** Submit application (no review by TGA, unless process relates to sterility or metrology or IVD medical device for point of care or self-testing)		**Class I:** Declaration (unless process relates to sterility or metrology)		**Class I:** Declaration (unless process relates to sterility or metrology)		**Class I:** Notification		**Class A:** Notification		**Class I:** Notification	**Class I and II (with predicate):** Notification (if substantially equivalent to device on market)	**Class I:** Submit application (no review by Health Canada)
	Timeframe: 24 hours for entry on ARTG		**Timeframe:** Immediate		**Timeframe:** Immediate		**Timeframe:** 5 business days		**Timeframe:** Immediate		**Timeframe:** Immediate	**Timeframe:** Immediate	**Timeframe:** On receipt of certificate
	For most countries, Class 1 devices require only notification and no premarket approval, such that devices may be marketed immediately or within a short period. Some countries also require compliance with GMP, with most also requiring manufacturer licensing.												
Higher risk devices	**Class IIa, IIb, III, 2 and 3:** Conformity assessment by TGA or comparable overseas regulator.		**Class IIa, IIb and III medical devices:** Conformity assessment by notified body.		**Class IIa, IIb and III medical devices:** Conformity assessment by notified body.		**Class II:** Simplified registration by Anvisa.		**Class B – D:** Conformity assessment by HSA. Nature of assessment influenced by prior approvals reference regulatory agencies and safe marketing history.		**Class II and III with certification standards:** Conformity assessment by Registered Certification Body	**Class I and II (no predicate):** De Novo assessment by FDA.	**Class II, III and IV:** Medical device license required.

	Australia	UK	Netherlands	Brazil	Singapore	Japan	USA	Canada
	Timeframe: Conformity assessment timeframes generally not available as more than 90% use overseas certification. 20 TGA business days for market authorisation (or selection for audit – additional 30 to 60 TGA business days).	**Timeframe:** Target timeframe of 242 business days. *No breakdown of actual time because notified bodies are private commercial.*	**Timeframe:** Ministry expects timeframe of less than 193 days. *No breakdown of actual time because notified bodies are private commercial.*	**Timeframe:** Actual timeframe of approx. 104 business days.	**Timeframe:** 100 – 310 business days (based on whether assessment is expedited, abridged or full).		**Timeframe:** Actual timeframe of approx. 280 calendar days.	**Timeframe:** Actual timeframe of approx. 11-64 business days based on the Class of device. Note: this timeframe only includes the first review – if Health Canada requests additional information and undertakes further review, the clock is reset to zero.
	Class 4, Class III combination devices: Conformity assessment by TGA.			**Class III and IV:** Pre-market assessment by Anvisa.		**Class II and Class III without certification standards, Class IV:** Pre-market approval by PMDA	**Class III:** Premarket approval by FDA.	
	Timeframe: Statutory timeframe of 255 TGA business days. Actual average timeframe of 131 TGA business days (plus 5 TGA business days for market authorisation).			**Timeframe:** 107 – 146 business days (based on whether medical device or IVD and class of device).		**Timeframe:** Timeframe is set not by class but by the following classification from the viewpoint of novelty. New medical devices (priority review): 10 months (80 percentile)	**Timeframe:** Actual timeframe of approx. 345 business days.	

	Australia	UK	Netherlands	Brazil	Singapore	Japan	USA	Canada
						New medical devices (standard review): 14 months (80 percentile) Improved medical devices (with clinical data): 10 months (60 percentile) Improved medical devices: 6 months (60 percentile) Generic medical devices: 4 months (60 percentile)		
	For all countries, devices that are considered a moderate or high risk require some degree of independent assessment. The nature of the assessment (e.g. the conformity assessment procedures that must be applied, whether overseas approvals can be used as evidence and the body that must undertake the assessment) varies between countries and taking into account different factors. The nature of assessment (and as such, timeframes for assessment) are influenced by factors such as: the inherent risk/complexity of the device, whether full assessment is needed or an abridged assessment may be undertaken, how similar the device is to one already on the market, whether the device has been approved by another regulator, whether there have been any safety issues globally, the period for which the device has been on the market in other countries, etc.							

Introduction

Context

A Review of Medicines and Medical Devices Regulation (MMDR) was undertaken from 2014–15 to identify areas of unnecessary, duplicative, or ineffective regulation that could be streamlined and opportunities to enhance the regulatory framework, so that Australia continues to be well positioned to respond to emerging global trends. The Government accepted 56 recommendations that provide options to harmonise Australia's regulatory system for therapeutic products with international regulatory frameworks and allow for greater flexibility in approval pathways for medicines and medical devices.

Recommendation 21 of the MMDR Review suggested that the Therapeutic Goods Administration (TGA) establish target timeframes that reflect international benchmarks and the typical lifecycle of a medical device for:

- conformity assessments conducted by the TGA (referred to as pre-market approval); and
- recommendations about inclusion of a device in the Australian Therapeutic Goods Register (ARTG) following submission of an application for inclusion (referred to as market authorisation) where:
  - the TGA has undertaken conformity assessment
  - a comparable overseas body has undertaken conformity assessment and a full evaluation report and dossier have been provided to the TGA.

The review recommended that the Australian Government give consideration to appropriate statutory timeframes for the conduct of conformity assessments and for consideration of an application for inclusion of a medical device in the ARTG (with and without an application audit). Such timeframes should: reflect international benchmarks; reflect the lifecycle of medical devices; and take account of the different levels of complexity posed by different device classes.

Process

mpconsulting was engaged to undertake consultation within the TGA and with comparable overseas bodies to determine how international bodies regulate medical devices and examine how the TGA's approach and timeframes compare with international regulators.

mpconsulting and the TGA participated in consultations with the following international regulators:

- Brazil: the Brazilian Health Regulatory Agency (Anvisa)
- Singapore: the Health Sciences Authority
- United Kingdom: the Medicines and Healthcare products Regulatory Agency (MHRA)
- Japan: the Pharmaceutical and Medical Device Agency (PMDA) and Ministry of Health, Labour and Welfare
- Canada: Health Canada
- United States: the Food and Drug Administration (FDA).

To facilitate discussions with international regulators, mpconsulting worked with the TGA to develop a summary of TGA processes and timeframes for regulation of medical devices in Australia (Attachment A).

Overview of TGA approach to regulation of medical devices

The Australian medical devices regulatory framework is based on the principles of medical device regulation developed by the Global Harmonization Task Force (GHTF). The regulatory systems of both the European Union and Australia are based on the GHTF model, and as a result, the Australian and European systems of device regulation are closely aligned for medical devices, though not identical (and, unlike Australia, most IVDs in Europe are currently self-certified). Other GHTF[1] members have also implemented elements of the GHTF model to varying extents.

The TGA adopts a risk-based approach to regulating therapeutic goods to ensure that the level of regulation matches the risks posed by particular therapeutic goods.

Classes of medical devices

The manufacturer is responsible for classifying a medical device (in line with Division 3.1 of the *Therapeutic Goods (Medical Device) Regulations 2002*), which determines the requirements for the conformity assessment procedures the manufacturer must apply to that device. The higher the risk of the device, the higher the requirements of the conformity assessment procedures.

The class of medical devices in Australia are outlined below.

Class	Risk level	Examples
Medical devices		
Class I	Low	Surgical retractors, tongue depressors
Class I – supplied sterile Class I – incorporating a measuring function Class IIa	Low-medium	Hypodermic needles, suction unit
Class IIb	Medium-high	Lung ventilator, blood bags, condoms
Class III	High	Heart valves, major joint replacement implants, combination devices (containing medicines or tissues, cells or substances of animal, biological or microbiological origin)
AIMD (Active Implantable Medical Devices)	High	Implantable defibrillator
IVDs		
Class 1 IVD	No public health risk or low personal risk	microbiological culture media, instruments/analysers
Class 2 IVD	Low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits, cholesterol test
Class 3 IVD	Moderate public health risk or high personal risk	Tests to detect a sexually transmitted disease, human genetic tests
Class 4 IVD	High public health risk	Blood donor screening tests for HIV, test for Ebola

[1] The GHTF was replaced by the International Medical Device Regulators Forum (IMDRF) from October 2011.

Regulation of medical devices

The regulatory framework for medical devices spans the life of the device and includes:

1. pre-market assessment: conformity assessment (whether undertaken by the TGA or a third party conformity assessment body)
2. market authorisation: inclusion on the ARTG
3. post-market monitoring: continuing compliance with all regulatory, safety and performance requirements and standards.

The split of the pre-market assessment and the market authorisation steps reflects that, more than 90% of applications for inclusion on the ARTG use overseas conformity assessment authorisation, e.g., European notified bodies' EC certificates to support ARTG entry. Since October 2018, use of market authorisation evidence from comparable overseas regulatory bodies for medical devices, including IVDs, has been expanded to include regulatory approvals from other comparable overseas regulators:

- notified bodies designated by the medical device regulators of European member states, under the medical device regulatory frameworks of the European Union
- the USFDA
- Health Canada
- the Japanese Ministry of Health, Labour and Welfare and the PMDA (not IVDs)
- Medical Device Single Audit Program (MDSAP) Auditing Organisation.

Pre-market assessment

Approach

Independent certification of the manufacturer's conformity assessment procedure is required for all but Class I (low risk) devices (which can be self-certified by the manufacturer).

The applicant must be able to demonstrate that the appropriate conformity assessment procedure (or requirements comparable to the conformity assessment procedures) has been applied and that the device complies with the Essential Principles in line with their intended purpose and risk-based classification. The Essential Principles set out the fundamental design and manufacturing requirements for medical devices.

This can be demonstrated by providing appropriate certification issued to the manufacturer by an appropriate conformity assessment body:

- For some specific high-risk devices, manufacturers must hold a conformity assessment certificate issued by the TGA as per Regulation 4.1 of the *Therapeutic Goods (Medical Device) Regulations 2002*. This applies where medical devices contain medicines or tissues, cells or substances of animal, human, microbial or recombinant origin; or for Class 4 IVD medical devices. Manufacturers may also choose to seek TGA conformity assessment.
- For other medical devices (given the close parallels between the European and Australian medical device regulatory frameworks) the TGA generally accepts conformity assessment certification (EC Certificates) from European notified bodies issued under relevant European Directives or Regulations, and a range of approvals from Comparable Overseas Regulators.

Timeframes

Timeframes for TGA conformity assessment of lower risk medical devices cannot be quantified. Manufacturers of these devices (devices not requiring TGA conformity assessment certification under Regulation 4.1) generally use overseas authorisation as evidence for inclusion onto the ARTG. There is no differentiated statutory timeframe for cases where a manufacturer chooses to apply for TGA conformity assessment certification for a lower risk medical device compared to a higher risk device.

Regulation 4.3 specifies that applications for TGA conformity assessment that require a Design Examination are subject to a statutory timeframe of 255 business days. This is applicable to higher risk devices that require TGA conformity assessment certification under Regulation 4.1.

In practice, applications for TGA conformity assessment certification of new devices (for all classes of medical devices, noting this is predominantly for high-risk devices) take an average of 131 TGA business days, while TGA conformity assessment applications for substantial changes to existing devices take an average of 110 TGA business days.

Market authorisation

Approach

Medical devices must be included on the ARTG before they can be lawfully supplied in, imported into or exported from Australia. Applications must be supported by conformity assessment certification from the TGA (or parallel documents from Comparable Overseas Regulators (EU, USA, Canada, Japan, MDSAP)).

The TGA may approve the inclusion of a device in the ARTG based on the information provided in the application or select an application for audit assessment. Applications for some medical devices must be selected for audit, including applications for:

- Class III, AIMDs and Class IIb medical devices where the manufacturer's conformity assessment certification was issued by a European notified body.
- certain IVD medical devices (e.g. those intended for self-testing or use at the point of care; for detection of sexually transmitted diseases; or Class 3 IVD medical devices where suitable evidence of product assessment by a comparable overseas regulator has not been provided).

The scope of any audit is based on any issues identified by the TGA as requiring further scrutiny.

Timeframes

Timeframes for inclusion on the ARTG are as below:

- for Class I medical devices: within 24 hours of application unless subject to mandatory application audit (e.g. IVDs for point of care or self-testing)
- for medical devices that have received conformity assessment certification from the TGA: within 5 TGA business days
- for all other medical devices: within 20 TGA business days unless subject to mandatory application audit.

The TGA must select an application for audit within 20 TGA business days. The TGA has target timeframes for application audits of between 30 and 60 business days for medical devices (non-IVD), but sometimes exceeds these timeframes:

- for Class I (measuring or sterile), Class IIa and Class IIb medical devices: if selected for audit, audits are completed in an average of 58 TGA business days

- for Class III and AIMD medical devices:
  - Level 1 audits are completed in an average of 33 TGA business days (target of 30 working days)
  - Level 2 audits are completed in an average of 83 TGA business days (target of 60 working days)
- for Class 2 and Class 3 IVD medical devices:
  - non-compulsory audits are completed in an average of 57 TGA business days
  - compulsory audits are completed in an average of 81 TGA business days.

Post-market monitoring

Approach

Once a device is approved, manufacturers are expected to continue to monitor 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 and will be periodically checked by the certifying body (whether this is the TGA or another conformity assessment body).

The 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 should be used by the manufacturer to review the quality, performance, safety and benefit-risk assessment of the device.

Post-market monitoring by the TGA is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market. This includes:

- risk assessment and investigation of medical device adverse event and complaint reports
- checking evidence of conformity against the Essential Principles
- conducting periodic audits of manufacturers' quality management systems and technical documentation
- imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents and other information involving their medical devices.

Timeframe

Post-market monitoring undertaken by the TGA is ongoing for the life cycle of the device.

International approaches

European Union

The European regulatory framework for medical devices most closely aligns with that of Australia, including the classes of medical devices and conformity assessment processes. However, for IVD medical devices, regulatory frameworks only align for Class4 IVDs as lower risk IVDs are predominantly self-certified in Europe.

Medical devices in the European Union (EU) are currently regulated by three directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD)
- Council Directive 93/42/EEC on Medical Devices (MDD)
- Council Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDMD).

To sell a medical device in the EU, manufacturers must demonstrate that the device meets the Essential Requirements outlined in the above directives (similar to Australia's Essential Principles) by carrying out a conformity assessment. As with the Australian system, the conformity assessment route depends on the classification of the device, with low risk products requiring self-declaration by the manufacturer and higher risk products requiring third party assessment by notified bodies:

- Class I devices:
  - manufacturer must declare that device complies with the requirements in the MDD
  - where manufacturing processes relate to sterility or metrology, these parts must be certified by a notified body
- Class IIa devices: manufacturer must declare that device complies with the requirements in the MDD and a notified body must undertake conformity assessment
- Class IIb devices: a notified body must undertake conformity assessment
- Class III devices: a notified body must undertake conformity assessment.

For IVD medical devices, only a small proportion of high-risk devices are required to undergo review from a notified body, while the majority of IVDs are self-certified.

Notified bodies are organisations that have been designated by the medical device regulators of EU member states to undertake conformity assessments of medical devices. Notified bodies are independent, accredited bodies that are verified by an authorised accrediting body. The legislation outlines competence, impartiality and independence criteria/obligations for notified bodies carrying out third-party assessment.

A notified body may undertake a maximum of three rounds of conformity assessment. If, on completion of the third round, the notified body is still not satisfied that the manufacturer has demonstrated the device meets the Essential Requirements, a decision must be made to reject the application.

Once a notified body has completed a conformity assessment of a medical device, it may designate that the device conforms to the EU MDD, and can be distributed and sold in the EU. The EU member state accrediting the notified body will then inform the European Commission that the product complies with the Essential Requirements.

While Australia splits pre-market assessment and market authorisation, medical devices in the EU can go straight to market once their pre-market assessment has been approved.

Member states are required to control the market and undertake post-market review of medical devices. Manufacturers must report adverse incidents with a medical device to the relevant medical device regulator where the incident happened (competent authority).

United Kingdom

Approach

The approach to regulation of medical devices in the UK is as described above for the European Union.

The medical device regulator in the UK is the Medicines and Healthcare products Regulatory Agency (MHRA).

The UK is looking to introduce a register of approved devices; however, this will not act as an additional pre-market requirement (as per the ARTG) but provide notification/identification of approved devices.

Timeframes

As notified bodies in the EU are private commercial entities, data regarding the actual timeframes for conformity assessments is not available.

There are no legislated or target timeframes for the processing of applications for conformity assessment of medical devices in the UK. However, the MHRA expects most applications to be processed within less than one year (approximately 242 business days for the purposes of comparison with the TGA).

Unlike the Australia system, manufacturers may not use overseas certification to support access to the EU market.

The Netherlands

Approach

The approach to regulation of medical devices in the Netherlands is as described above for the European Union.

The medical device regulator in the Netherlands is the Ministry of Health, Welfare and Sports.

Timeframes

As notified bodies in the EU are private commercial entities, data regarding the actual timeframes for conformity assessment is not available.

There are no legislated or target timeframes for the processing of applications for conformity assessment of medical devices in the Netherlands.

The Ministry of Health, Welfare and Sports expects that conformity assessments usually take approximately nine months (approximately 193 business days for the purpose of comparison with the TGA). However, this can vary significantly depending on the classification of the device

and the quality of the files submitted with the application. In discussion, the Ministry advised that, the files submitted by applicants are not always of the required quality, which can lead to much back and forth between the applicant and the notified body as they request additional information and clarification.

Brazil

Approach

Medical devices in Brazil are regulated by the Brazilian Health Regulatory Agency (Anvisa).

Anvisa categorises medical devices into four types for the purpose of regulation:

- medical equipment – regulated by Resolution RDC 185/2001 and RDC 40/2015
- materials for health use – regulated by Resolution RDC 185/2001 and RDC 40/2015
- orthopaedic implants – regulated by Resolution RDC 185/2001
- in vitro diagnostics – regulated by Resolution RDC 36/2015.

Medical devices in Brazil are classified by risk similarly to in Australia:

Class	Risk level	Examples
Medical devices		
I	Low	Surgical retractors, tongue depressors
II	Low-moderate	Hypodermic needles, suction unit
III	Moderate-high	Lung ventilator, implants for hip, knee or shoulder replacement, implantable defibrillator
IV	High	Coronary stent
IVDs		
I	Low	Microbiological culture media, analysers/instruments
II	Low-moderate	Pregnancy and fertility self-testing kits, cholesterol test
III	Moderate-high	Tests to detect a sexually transmitted disease, genetic tests, tests for Ebola
IV	High	ABO compatibility test, blood donor screening tests, tests for HIV

The pre-market and market authorisation steps are combined in Brazil, as Brazil does not accept overseas approvals in place of Anvisa pre-market approvals. However, MDSAP audit reports can be used as evidence for the issuance of GMP certificates by Anvisa.

Anivsa requires that companies that manufacture medical devices for supply in Brazil comply with Good Manufacturing Practices (GMP) and issues a GMP certificate to attest that a particular manufacturer complies with GMP.

Market authorisations are issued by Anvisa and depend on the risk classification of the medical device:

- for devices (including IVDs) categorised as Class I:
  - GMP requirements must be followed but there is no requirement for Anvisa GMP certification
  - the manufacturer may be inspected by Anvisa to verify compliance with GMP requirements

  - company licensing with notification to Anvisa
  - market authorisations do not expire but may be cancelled in some circumstances
- for devices (including IVDs) categorised as Class II:
  - GMP requirements must be followed but there is no requirement for Anvisa GMP certification
  - the manufacturer may be inspected by Anvisa to verify compliance with GMP requirements
  - company licensing with 'Cadastro' (i.e. a simplified registration process) applies
  - market authorisations do not expire but may be cancelled in some circumstances
- for devices (including IVDs) categorised as Class III and Class IV:
  - the manufacturer requires State licensing
  - a valid GMP certificate (issued by Anvisa) is a requirement for Anvisa to issue a market authorisation for these products
  - pre-market approvals are valid for ten years from the date of their publication in the Brazilian Official Gazette and may be renewed for equal and successive periods.

Timeframes

Timeframes for the authorisation of medical devices in Brazil are broadly as per below:

- Class I medical devices: 7 calendar days (approximately 5 business days for the purpose of comparison with the TGA)
- Class II medical devices: 145 calendar days (104 business days)
- Class III and Class IV medical devices: 205 calendar days (146 business days)
- Class II IVD medical devices: 7 calendar days (5 business days)
- Class II IVD medical devices: 105 calendar days (75 business days)
- Class III and Class IV IVD medical devices: 150 calendar days (107 business days).

Singapore

Approach

Singapore's Health Sciences Authority (HSA) commenced regulation of medical devices in 2010.

The laws regulating medical devices sold in Singapore are the Health Products Act and Health Products (Medical Devices) Regulations (the Regulations). All product manufacturers are required by law to register their medical devices and obtain a dealer's licence with HSA before selling or dealing with them.

Singapore's regulation of medical devices is based on GHTF principles. The medical device classification rules are outlined in GN-13: Guidance on the Risk Classification of General Medical Devices and IVD risk classification rules are outlined in GN-14: Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices.

Medical devices are classified as below.

Class	Risk level	Examples
Medical devices		
A	Low	Surgical retractors, tongue depressors
B	Low-moderate	Hypodermic needles, suction equipment
C	Moderate-high	Lung ventilator, bone fixation plate
D	High	Heart valves, implantable defibrillator
IVDs		
A	Low	Specimen collection tubes, general culture media
B	Low-moderate	Pregnancy tests, Anti-Nuclear Antibody tests, urine test strips
C	Moderate-high	Blood glucose tests, HLA typing tests, PSA screening tests, Rubella tests
D	High	Screening for HIV, ABO blood grouping tests

The pre-market and market authorisation steps are combined in Singapore. For all devices, Singapore uses overseas certification to abridge pre-market evaluation but not in place of pre-market authorisation from the HSA.

Medical devices must comply with the Essential Principles for Safety and Performance for Medical Devices as specified in the Regulations prior to their placement on the Singapore market.

Class A medical devices are exempt from product registration and can be immediately supplied to the market without going through the product registration. The information published on the Class A Medical Device Register is self-declared by the manufacturers and is not verified by HSA.

All Class B, C and D medical devices (including IVDs) must undergo pre-market evaluation. For these medical devices, four evaluation routes exist. These are described in GN15: Guidance on Medical Device Product Registration:

- **full:** undertaken when the device has not obtained any prior approval from any of HSA's reference regulatory agencies at the point of application
- **abridged:** an abbreviated evaluation using existing evidence/approvals
  - for Class B, C or D devices that have obtained at least one reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore
- **immediate:** an online application (including verification by HSA) is completed to include the device in the Singapore Medical Device Register:
  - for Class B devices that have obtained at least one reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore; no rejections/withdrawals; no safety issues globally; and have been marketed for at least three years
  - for Class B devices that have obtained at least two approvals from reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; no rejections/withdrawals; no safety issues globally
  - for some Class C devices that have obtained at least one reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore; no rejections/withdrawals; and no safety issues globally
- **expedited:**
  - for some Class C devices that have obtained at least one reference regulatory agency approval for a labelled use identical to that intended for marketing in Singapore; no

rejections/withdrawals; no safety issues globally; and have been marketed for at least three years

- for some Class C devices that have obtained at least two approvals from reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; and have no rejections/withdrawals
- for some Class D devices that have obtained at least two approvals from reference regulatory agencies for a labelled use identical to that intended for marketing in Singapore; and have no rejections/withdrawals.

The evaluation routes are set out on a confidence-based approach, leveraging on safe marketing history and prior recognised approvals from reference agencies (EU, USA, Australia, Japan, Canada). Documentary requirements for evaluation differ according the evaluation route and risk class of the medical device.

To qualify for the immediate or expedited evaluation routes, the medical device must not have been rejected or withdrawn by any foreign regulatory agency or HSA due to quality, performance/efficacy or safety issues; and must have no safety issues globally associated with the use of the device when used as intended by the product owner, in the last three years.

The Priority Review Scheme provides the option for applicants to gain faster registration and market entry for their medical devices that are submitted to HSA through the full evaluation route if a Class B, C or D medical device fulfils qualification criteria.

HSA undertakes post-market monitoring of medical devices once they are registered. Manufacturers must notify HSA of any changes, report adverse events to HSA and report Field Safety Corrective Actions to HSA.

Timeframes

HSA has published target processing timeframes for applications for registration/pre-market evaluation of medical devices:

Class	Target timeframes for registration (business days)				
	Immediate	**Expedited**	**Abridged**	**Full**	**Full (priority)**
B	Immediate registration	N/A	100	160	120
C	Immediate registration (for some)	120	160	220	165
D	N/A	180	220	310	235

Class	Target timeframes for change notification (business days)		
	Review changes	**Administrative changes**	**Technical changes**
B	45	30	N/A
C	N/A	30	75
D	N/A	30	90

Actual timeframes for full pre-market assessment and market authorisation of medical devices are (as advised by the HSA) on average significantly shorter than the published target timeframes:

- Class B: average 78 business days
- Class C: average 110 business days
- Class C: average 120 business days.

Japan

Approach

In Japan, medical devices are regulated by the Pharmaceutical and Medical Device Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW). The PMDA is an independent agency that works with the MHLW to assess the safety and effectiveness of medical devices. Current Japan PMDA regulations are laid out in the Pharmaceuticals and Medical Devices Act (PMD Act).

Similar to Australia, Japan uses a risk-based classification system to categorise medical devices into four classes based on the associated risk:

Class	Risk level	Examples
I	Extremely low	X-ray film, scalpels, some IVD devices
II	Moderately low	Digestive catheters, electronic endoscopes, dental alloys
III	Relatively high	Dialysers, haemodialysis equipment, mechanical ventilation apparatuses
IV	Very high	Artificial cardiac valves, pacemakers and stent grafts

- Class I devices are considered General Medical Devices and only require notification/self-declaration.
  - The device does not need to undergo an approval process by the PMDA and MHLW.
- Class II devices may be categorised as either Controlled Medical Devices or Designated Controlled Medical Devices
  - Designated Controlled Medical Devices must be certified by a Registered Certification Body (RCB).
  - Controlled Medical Devices must be reviewed by the PMDA and MHLW.
- Class III and Class IV devices are considered Specially Controlled Medical Devices
  - Class III devices with certification standards must be certified by the RCB.
  - Class III devices without certification standards and Class IV devices must be reviewed by the PMDA and MHLW.

For the purpose of undertaking review of medical devices, the PMDA has introduced a 3-track review system:

- **new medical devices:** those with a clearly different structure, usage, performance, etc. compared with those for which marketing approval has already been granted
- **generic medical devices:** those regarded as substantially equivalent to existing approved medical devices in terms of structure, usage, performance, etc.
- **improved medical devices:** those that do not fall under new medical devices or generic medical devices.

Overseas approvals are not accepted by the PMDA for the purposes of accessing the Japanese market or abridging assessments.

The PMDA undertake post-market surveillance and monitoring. Device registrations in Japan do not expire, but manufacturers' QMS certificates must be renewed every five years.

Timeframes

Review timeframes for new medical devices in 2018 are published in the PMDA's Annual Report[2]:

- New medical devices (priority review):
  - Target: 80% reviewed within 10 months (approximately 214 business days for the purpose of comparison with the TGA).
  - Actual: the target was exceeded, with 80% of the devices reviewed within 8.3 months.
- New medical devices (standard review):
  - Target: 80% reviewed within 14 months (approximately 300 business days)
  - Actual: the target was exceeded, with 80% of the devices reviewed within 12.0 months (approximately 255 business days).
- Improved medical devices (with clinical data):
  - Target: 60% reviewed within 10 months (approximately 214 business days).
  - Actual: the target timeframe was exceeded, with 60% of the devices reviewed within 8.8 months (approximately 189 business days).
- Improved medical devices:
  - Target: 60% reviewed within 6 months (approximately 130 business days).
  - Actual: the target was achieved, with 60% of the devices reviewed within 5.7 months (approximately 124 business days).
- Generic medical devices:
  - Target: 60% reviewed within 4 months (approximately 86 business days).
  - Actual: the target was exceeded, with 60% of the devices reviewed within 3.5 months (approximately 74 business days).

United States

Approach

The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is responsible for regulating medical devices sold in the United States.

Medical devices, including IVD medical devices, are classified into Class I, II, and III based on the risk of the device, with regulatory control increasing from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type.

Class	Risk level	Examples	Regulation
I	Lowest risk	Manual toothbrushes	subject to general controls
II	Moderate risk	Male condoms, non-invasive blood pressure monitors	subject to general controls and special controls

[2] Pharmaceuticals and Medical Devices Agency, Japan, *Annual Report FY 2018 (April 2018-March 2019)*, pp. 98 112.

Class	Risk level	Examples	Regulation
III	Highest risk	Heart valves	subject to general controls and premarket approval

To supply a medical device in the United States, manufacturers must:

- undertake the required premarket submission process:
  - 510(k) (Premarket Notification)
    - Required for some Class I and most Class II devices.
    - Sponsor must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States.
  - De Novo (Evaluation of Automatic Class III Designation)
    - Required for new Class I or Class II devices where there is no substantially equivalent device in legal commercial distribution in the United States (i.e. no valid predicate).
  - PMA (Premarket Approval)
    - Required for most Class III devices.
    - Sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use.
  - HDE (Humanitarian Device Exemption)
    - Required for Class III devices that are intended to benefit patients with rare diseases or conditions (usually with limited clinical evidence available).
- electronically register their establishment with the FDA annually (Title 21 CFR Part 807)
- list their devices with the FDA, including certain information (Title 21 CFR Part 807).
- demonstrate that their manufacturing practices meet the Quality System Regulation (21 CFR 820) or Good Manufacturing Practices.

Timeframes

The FDA provided a number of reports including data on their timeframes for undertaking assessment of applications.[3,4]

- For Pre-Market Approvals in 2016, the average time to decision was 345 days (which comprised 167 FDA days and 178 submitter days)
- For 510(k)s in 2016, the average time to decision was 141 days (which comprised 74 FDA days and 67 submitter days)
- For De Novos in 2016, the average time to decision was 280 days (which comprised 176 FDA days and 104 submitter days).

[3] Quarterly Update on Medical Device Performance Goals – MDUFA IV CDRH Performance Data – Action through 31 Dec 2018, 22 February 2019.
[4] FDA, FY 2017 – Performance Report to Congress for the Medical Devices User Fee Amendments.

The FDA has published the below proposed target timeframes from submissions received in 2020 through 2022:

- for PMA submissions, the average total time to decision goal for FDA and industry is 290 calendar days
- for 510(k) submissions, the average total time to decision goal for FDA and industry is 108 calendar days.[5]

Canada

Approach

Health Canada reviews medical devices to assess their safety, effectiveness and quality before being authorised for sale in Canada. The Medical Devices Regulations regulate medical devices offered for sale in Canada to ensure they are safe, effective and of high quality.

Consistent with international approaches, Canada divides medical devices, including IVD medical devices, into different classes based on risk. There are four classes of devices in Canada:

Class	Risk level	Examples
I	Lowest potential risk	Wheelchairs, hospital beds, gauze bandages, surgical/dental instruments
II	Low-moderate potential risk	TENS units, contact lenses, surgical gloves, digital thermometers, powered toothbrushes
III	Moderate potential risk	Dental crowns, orthopaedic implants, insulin infusion pumps, blood glucose monitors, neonatal heart rate monitors
IV	Highest potential risk	Bone grafts, HIV test kits, pacemakers, tissues heart valves, neurosurgical shunts

Medical device manufacturers must undergo quality management system certification to confirm that the quality management system under which the device is manufactured satisfies the requirements of *ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes*.

Prior to selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a Medical Device Licence. Although Class I devices do not require a Licence, they are monitored through Establishment Licences.

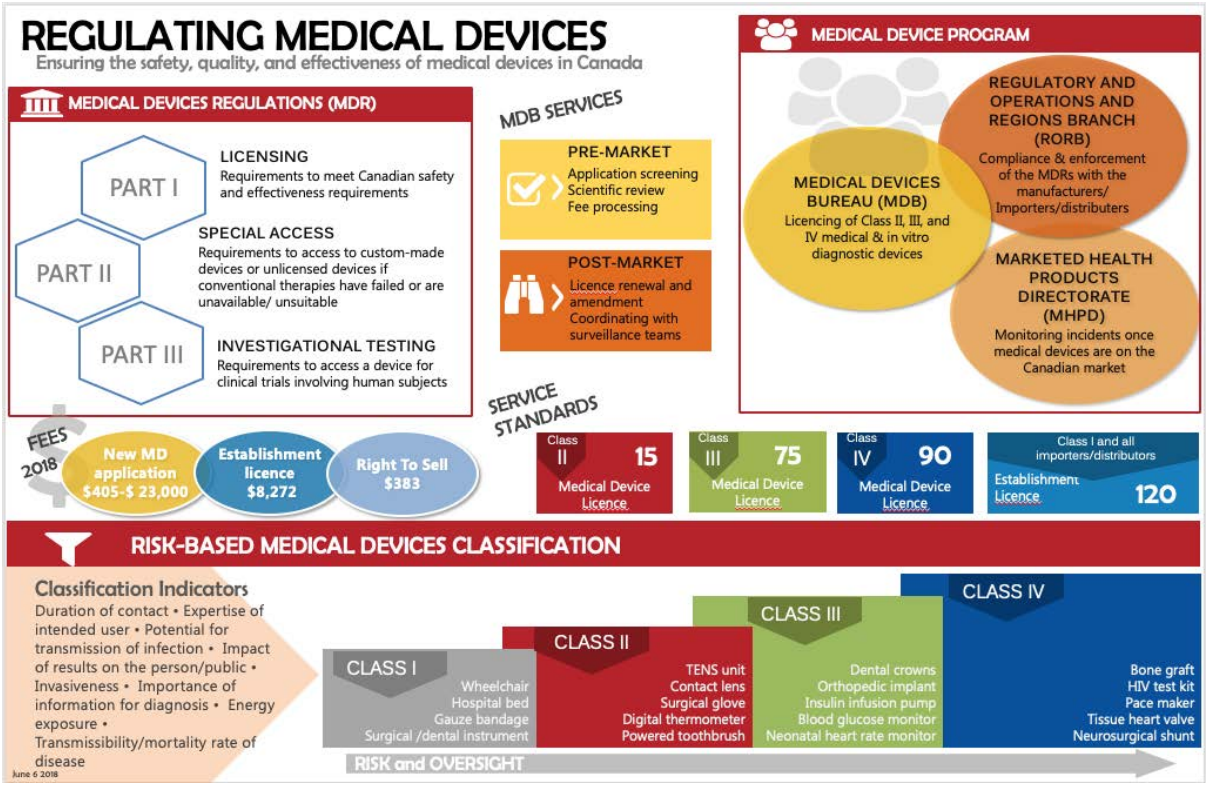
Establishment Licencing requires manufacturers of medical devices for sale in Canada to provide assurance to Health Canada that regulatory requirements related to post-production activities are met.

Manufacturers that wish to market a medical device in Canada, must submit a Medical Device Licence Application to Health Canada. The amount of information required in the application varies depending on the class of the device. If Health Canada determines that information provided meets the requirements of the Medical Devices Regulations, a Licence is issued. Health Canada does not accept overseas authorisations in place of a Medical Device Licence Application.

[5] FDA, MDUFA Performance Goals and Procedures, fiscal years 2018 through 2022.

Health Canada also plays a role in monitoring medical devices after they are licensed to ensure their continued safety and effectiveness.

The below diagram was provided by Health Canada and provides an overview of medical device regulation in Canada.



Timeframes

The length of the review varies depending on the class of the device and the quality of information provided by the applicant (and number of times Health Canada needs to liaise with/request additional information from applicants). Health Canada publishes target review timeframes:

- Class II Licence applications
  - Complete review – 15 calendar days from date of receipt (11 business days for the purposes of comparison with the TGA)
- Class III Licence applications
  - Step 1: screening for regulatory and admin completeness and cursory review of scientific content – 15 calendar days (11 business days)
  - Step 2: complete review – 75 calendar days (54 business days)
- Class IV Licence applications
  - Step 1: screening for regulatory and admin completeness and cursory review of scientific content – 15 calendar days (11 business days)
  - Step 2: complete review – 90 calendar days (64 business days).

The QMS process is completed prior to the application for a Medical Devices Licence, so is not included in these timeframes. Timeframes for QMS assessment are commercial so are not available for comparison.

Health Canada may request additional information during the screening or review phases. If additional information is required:

- for Class II devices, manufacturers have 15 days to respond and Health Canada has 15 days to review if this is sufficient
- for Class III and Class IV devices, manufacturers have 60 days to respond and Health Canada has 45 days to review if this is sufficient.

This cycle can be repeated as required. Performance timeframes are based on completion of the first review.

Attachment A: Timeframes for regulation of medical devices in Australia

Approach

Life cycle	Requirements	Timeframes[6]
1. Pre-market approval Conformity assessment (CA) at a level commensurate to the risk of the device	• Independent certification of the manufacturer's CA procedure is required for all but low risk devices (which can be self-certified by the manufacturer). • TGA CA certification available on application. • TGA CA certification required for combination medical devices (e.g. containing medicines, Class 4 IVDs etc.).[7]	• TGA CA certification must be completed in **255 TGA business days** (statutory requirement).[8] – Generally completed in less than 200 days.
2. Market authorisation Medical devices must be included on the ARTG before they can be lawfully supplied in, imported into or exported from Australia	• Applications must be supported by CA certification (or parallel documents from Comparable Overseas Regulators (EU, USA, Canada, Japan, MDSAP)). • Approvals from Comparable Overseas Regulators may also be used to support applications to include a device on the ARTG.[9] • In practice, most CA certification is usually from EU notified bodies (timeframes are commercial).	• Applications for ARTG inclusion must be approved or selected for audit within **20 TGA business days** (statutory requirement). – This timeframe is always met. • If using TGA CA certification (or for MRA certification) ARTG inclusion is approved within **5 TGA business days**. • Target timeframe for Level 1 application audits is **30 TGA business days** and for Level 2 application audits is **60 TGA business days** (not enforceable by law) for medical devices. – Recently exceeding these estimates for mandatory (high risk) audits.[10]

[6] For a more detailed overview, see https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction
[7] *Therapeutic Goods (Medical Devices) Regulations 2002*, Regulation 4.1 prescribes devices required to hold TGA CA certification for supply in Australia
[8] TGA's Annual performance statistics report: July 2017 to June 2018 tables 31 and 33 provide conformity assessment application volumes and timeframes.
[9] Comparable overseas regulators arrangements outlined at https://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications. Details of comparable overseas regulators documents required to support applications for inclusion in the ARTG (for each classification) detail at https://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds (particularly Application Requirements - Table 2 of that document).
[10] TGA's Annual performance statistics report: July 2017 to June 2018 table 36 provides application audit volume and timeframes.

Life cycle	Requirements	Timeframes[6]
3. Post-market monitoring Continuing compliance with all regulatory, safety and performance requirements and standards	• Manufacturers maintain CA as part of the quality management system – this is periodically checked by the certifying body. • TGA undertakes post-market vigilance and monitoring to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market, including monitoring and risk assessment of adverse events and complaints • Sponsors are responsible for reporting (e.g. adverse events), distribution records, etc.	• Ongoing (for duration of supply, and in some cases beyond). • No set timeframes.[11]

Timeframes

Classification	Example	Pre-market approval requirements[12]	Overseas approvals accepted?	Pre-market approval timeframe	Market authorisation timeframe
Medical Devices[13]					
Class I Low risk	Reusable surgical retractors, tongue depressors	Auto-included in ARTG based on manufacturer self-certification	N/A	N/A	Completed within 24 hours of application
Class I – measuring Low to medium risk	Thermometer, prosthesis sizer	Product or production quality assurance	May use EU certification[14]	**Timeframes not available.** • TGA CA certification not required. • More than 90% of all products use overseas CA certification, very few lower risk products seek TGA CA.	**20 TGA business days.** TGA selects some applications for audit. • If selected, audit completed within average **58 TGA business days**.
Class I – sterile Low to medium risk	Sterile bandage, sterile surgical drapes	Production quality assurance			
Class IIa Low to medium risk	Hypodermic needles, suction unit	Full quality assurance excluding design examination, or declaration of conformity procedures and production quality assurance or	May use EU certification or approvals from Japan, Canada, or the USA (de novo or 510k)[14]		

[11] TGA's Annual performance statistics report: July 2017 to June 2018 tables 38 to 40 provide volume and timeframes for post market reviews and incident reports.
[12] TGA conformity assessment certificate for medical devices issued under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.
[13] Medical device classification rules outlined in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.
[14] Comparable overseas regulator equivalent certificates or documents outlined in Table 2 of the Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs).

Classification	Example	Pre-market approval requirements[12]	Overseas approvals accepted?	Pre-market approval timeframe	Market authorisation timeframe
		product quality assurance for non-sterile devices		• If seeking TGA CA certification, timeframes as below.	
Class IIb Medium to high risk	Lung ventilator	Full quality assurance excluding design examination, or type examination and product or production quality assurance			
Class III High risk	Heart valves, implants for hip, knee or shoulder replacement	Full quality assurance including design examination, or type examination and production quality assurance			**20 TGA business days** If using overseas certification, must undergo audit. Level 2 audit completed within average **83 TGA business days**.
Class III (combination products)	Devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin	Full quality assurance including design examination, or type examination and production quality assurance	Must have TGA CA certification. No use of comparable overseas regulatory approvals permitted[15]	Required within **255 TGA business days**. Actual timeframes: • New devices average **131 TGA business days** • Substantial changes and re-certifications) average **110 TGA business days**	**5 TGA business days**
AIMD High risk	Implantable defibrillator	Full quality assurance including design examination, or type examination and production quality assurance	May use EU certification or approvals from Japan, Canada, or the USA (PMA)[14]	**Timeframes not available.** • TGA CA certification not required. • More than 90% of all products use overseas CA certification; very few lower risk products seek TGA CA.	**20 TGA business days** If using overseas certification, must undergo audit. • Level 1 audit completed within average **33 TGA business days**

[15] Regulation 4.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* prescribes devices required to hold TGA CA certification for supply in Australia

Classification	Example	Pre-market approval requirements[12]	Overseas approvals accepted?	Pre-market approval timeframe	Market authorisation timeframe
				• If seeking TGA CA certification, timeframes as above.	• Level 2 audit completed within average **83 TGA business days**
IVDs[16]					
Class 1 No public health risk, low personal risk	Microbiological culture media, instruments/analysers	Auto-included in ARTG based on manufacturer self-certification (unless subject to application audit)	N/A	N/A	Completed within 24 hours of application (unless subject to application audit)
Class 2 Low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits, cholesterol test	Full quality assurance excluding design examination, or declaration of conformity procedures and production quality assurance	May use EU certification or approvals from Canada, MDSAP or ISO 13458[14]	**Timeframes not available.** • TGA CA certification not required. • More than 90% of all products use overseas CA certification; very few lower risk products seek TGA CA. • If seeking TGA CA certification, timeframes as per below.	**20 TGA business days.** TGA selects some applications for audit. If selected, audit completed within average **57 TGA business days**.
Class 3 Moderate public health risk or high personal risk	Tests to detect a sexually transmitted disease, genetic tests	Full quality assurance excluding design examination, or type examination and production quality assurance	May use EU certification or approvals from Canada, the USA (PMA), MDSAP or ISO13485[14]		
Class 4 High public health risk	Blood donor screening tests for HIV, test for Ebola	Full quality assurance including design examination, or type examination and production quality assurance	Must have TGA CA certification. No use of comparable overseas regulatory approvals permitted[15]	Required within **255 TGA business days**. Actual timeframes: • New devices average **131 TGA business days** • Substantial change or recertification application average **110 TGA business days**	**5 TGA business days**

[16] IVD classification rules outlined in Schedule 2A of the Therapeutic Goods (Medical Devices) Regulations 2002

Classification	Example	Pre-market approval requirements[12]	Overseas approvals accepted?	Pre-market approval timeframe	Market authorisation timeframe
In-house IVDs (laboratory developed tests)					
Class 1 No public health risk, low personal risk	Microscope counting chambers, microbiological culture media	Notification to TGA, supported by NATA accreditation	N/A	N/A	N/A
Class 2 Low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits, cholesterol test				
Class 3 Moderate public health risk or high personal risk	Tests to detect a sexually transmitted disease, genetic tests				
Class 4 High public health risk	Blood donor screening tests for HIV, test for Ebola	Full quality assurance including design examination, or GMP licence, or NATA accreditation	Must have TGA CA certification or alternative evidence of CA.	Required within **255 TGA business days.** Actual timeframes: • New devices average **131 TGA business days** • Substantial change or recertification application average **110 TGA business days**	**5 TGA business days if TGA CA used.** No applications received for use of alternative CA, so no information on this.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, TGA	November 2019

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #