As Australia only represents a relatively small fraction of the global medical device market, it may not be commercially viable for manufacturers to continue producing old versions of medical devices solely for supply in Australia. Australian patients may miss out on access to the latest medical technology already available in other developed economies (such as the EU and US) due to delays in the market approval process through TGA.

Many of these latest developments in medical technology (such as miniaturisation for minimally invasive surgery) are designed to reduce operating times and length of hospital stays, as well as improve recovery time and clinical outcomes for patients. Lack of timely access to technology is resulting in unnecessary cost pressure on an already stretched health system. Australian patients may be denied or experience delayed access to potentially life-saving technology.

Unique Australian requirements

It is a requirement in Australia that all devices are included in the ARTG prior to supply. This is an additional requirement to the regulatory system in Europe, where no central database of devices exists.

The ARTG is used as a resource by medical device manufacturers, sponsors, healthcare providers, government, patients and consumers to establish if a device has regulatory clearance to be supplied in Australia.

The ARTG provides the legislative basis for TGA to take action if a device no longer meets the requirements of the 'Essential Principles' or the sponsor of the device has not kept up their regulatory obligations.

Devices are included in the ARTG by device 'kind' (as defined in the *Therapeutic Goods Act 1989*). Most device entries cover a range of similar products rather than an individual model number. With the exception of high risk devices, which are individually included in the ARTG by product name or Unique Product Identifier(UPI).

For example if a consumer wants to check if their coronary stent is included in the ARTG, they would be able to enter the device model name in the ARTG search function and view an entry for the product (if it is still being supplied). This does not work for lower risk devices that are entered in the ARTG by device 'kind', as one entry in the ARTG may cover several different models of the same kind of device. For example a urinary bag supplied by a sponsor may have a single entry in the ARTG that covers a range of different models of urinary bag.

The ARTG has been criticised for not displaying that a specific device has been approved for supply in Australia and that the TGA does not know all of the devices that are available for supply in Australia based on the information held in the ARTG.

Sponsors of medical devices have also commented that the ARTG does not meet their needs by not naming models of products for lower risk classification devices. Some healthcare providers have not accepted evidence of product approval by TGA, even though the sponsor has an ARTG inclusion covering that kind of device.

Sponsors submitting an application for higher risk devices have also had to submit several applications to enter a 'device family' in the ARTG. For example, an orthopaedic hip implant may have been assessed by an EU Notified Body as a system of devices. This means that one part of the implant cannot work without the other parts of the system. Because of the mandatory use of Global Medical Device Nomenclature (GMDN) codes used to describe a 'kind' of device, a hip system has to be included in the ARTG by its component parts. Unless the reader is very familiar with the system, they may not be able to see that the entire system has been approved for supply by TGA. This also adds duplication to the review process. TGA assessors may have to review multiple sets of the same technical documentation to describe a single hip system.

The current structure of the ARTG does not appear to serve the purposes of the regulator, sponsor, consumer or healthcare provider. Sponsors of medical devices pay an annual charge to maintain each entry in the ARTG, and additional costs if they need to apply for a change to those ARTG entries. This in itself imposes an unnecessarily duplicative cost on the sponsor.

For example, a company who is the sponsor of over 1,000 ARTG entries for medical devices from one manufacturer is required to pay a fee of $400 per entry simply to have the manufacturer's name changed and updated in the ARTG. Due to the way the ARTG has been designed and the cost recovery arrangements of the TGA this amounts to over $400,000 for what should be a simple administrative task.

6. Opportunities for improvement to the Australian regulatory system

There are a number of ways to improve the current pre-market regulatory system for medical devices, without reducing the quality, safety or performance of devices supplied in Australia, and at the same time improving post-market monitoring and compliance of devices already on the market.

The opportunities for improvement can be briefly summarised as:

1. Changing the focus of TGA's involvement in pre-market assessment by:
    a. moving away from conducting conformity assessment reviews and taking on the role of a designating authority of third-party conformity assessment bodies
    b. ceasing to conduct duplicative pre-market assessments of medical devices already approved for supply by other similar regulatory bodies
    c. increasing oversight of other assessment bodies through existing international collaborations such as confidence building under the Mutual Recognition Agreement (MRA) with the EU, and the IMDRF Medical Devices Single Audit Program (MDSAP)
    d. improving internal systems to remove unnecessary and duplicative steps in the pre-market application process, and improving the functionality of IT systems and ARTG.
2. Increasing TGA resources devoted to post-market monitoring and compliance activities by moving resources previously involved in pre-market activities of limited value, and using them to conduct more valuable and efficient post-market activities.

The expected results of implementing these changes would include, but is not limited to, the following:

- quicker access to the latest medical technology for Australian patients
- a decrease in pre-market regulatory costs for Australian businesses
- more predictable processes and time frames for Australian businesses
- maintaining an equivalent level of quality, safety and performance to that of medical devices already on the market
- earlier detection of device failures and increased ability of TGA to react quickly, thereby reducing the number of Australians adversely affected by potentially unsafe devices

An overview of the proposed improved regulatory system is shown in Figure 2. This does not show all the possible pathways for supply, as there are many options available to sponsors, such as Clinical Trial and Special Access schemes which are not represented. TGA processing times and proportion (%) of devices subject to each time frame are estimates only based on a combination of previously reported target times from TGA, and the proportion of different device classifications included in the ARTG.

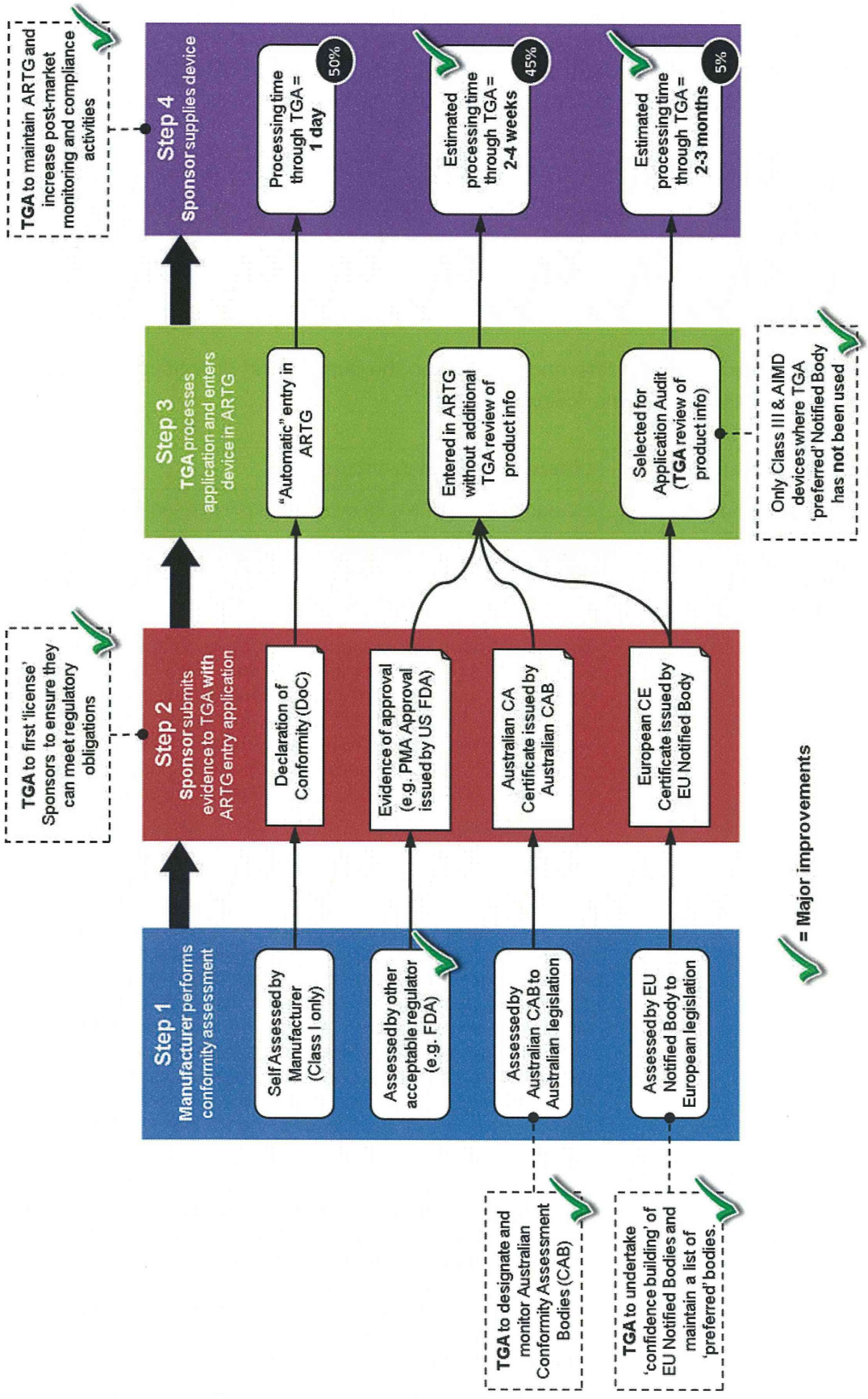

Figure 2 - Proposed Regulatory Supply Pathway for Medical Devices in Australia

A proposed improved regulatory system

The proposed regulatory pathway shown in Figure 2 includes a number of differences to the current system shown in Figure 1, many of which relate to the involvement of TGA at different stages in the pre-market assessment process.

It is important to note that these proposed changes do not affect the inherent product requirements and standards that must currently be met by all medical device manufacturers, such as the need to implement and maintain a QMS, and for all devices to comply with the Essential Principles for safety and performance.

The key features and main differences between the current and proposed regulatory pathways are described in the following table:

Proposed key features	Differences and advantages
1. TGA to designate third-party conformity assessment bodies to conduct assessments to Australian requirements.	Instead of performing its own conformity assessment reviews of manufacturers and devices, it would be more efficient use of TGA resources to act as a 'Designating Authority' in a similar way to EU Competent Authorities (such as the UK's MHRA). This would open the Australian market to competition from a number of assessment bodies who may wish to be designated to perform conformity assessment reviews according to Australian regulations. Increasing competition would likely result in decreasing costs and shorter assessment times for Australian businesses, compared to the current TGA monopoly on providing this service. Under the proposed system the TGA would assess a Conformity Assessment Body's (CAB) organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in medical device authorisations. TGA is renowned globally for astute auditing skills and these skills would easily be transferrable from medical device manufacturer audits to designating assessments of CABs. Once a CAB has been designated as appropriate for conducting assessments to Australian regulatory requirements, the TGA would conduct periodic audits to monitor and assess the quality of the medical device authorisations. This is a much more efficient way of ensuring that devices entering the market meet Australian regulatory requirements. TGA is already participating in a pilot scheme with three other International Medical Device Regulator Forum (IMDRF) members (Brazil, Canada and USA) and will be able to recognise QMS assessments conducted by Auditing Organisations (CABs) designated by the participating Regulatory Authorities. The Medical Device Single Audit Program (MDSAP) commenced in early 2014 and Auditing Organisation criteria has been documented. TGA's participation in the MDSAP program could be easily transferred to designation of Australian CABs to conduct both quality management system assessments and, for higher risk classification devices, design examinations.

Proposed key features	Differences and advantages
	MTAA has long argued that TGA's role as the pre-market evaluator and post-market regulator involves a degree of perceived conflict of interest, as there is no check of the quality of the conformity assessments it undertakes. The proposed model removes this ambiguity and provides the regulator with oversight of third-party assessment bodies.
2. TGA to build and maintain confidence in EU Notified Bodies.	Since most medical devices supplied in Australia will continue to be supported by CE certification issued by EU Notified Bodies, an important and necessary part of this model is for the TGA to build and maintain confidence in those bodies. By doing this the confidence of other stakeholders (such as patients and health professionals) in the Australian regulatory system would be improved, and it would allow the TGA to move its limited resources into increased post-market activities by lessening it's involvement in pre-market reviews and avoiding unnecessary duplication of effort. If TGA were to maintain a 'preferred' Notified Body (NB) list (those that they have successfully undertaken confidence building activities), then this would serve as a point of difference between those manufacturers using recognised competent NBs, and those using NBs of less well known origin and abilities.
3. TGA to no longer conduct conformity assessment certification reviews.	Instead of requiring Australian manufactured devices, and the sub-set of high risk devices designated by the regulations (those containing medicines or animal origin materials), to obtain TGA issued certification, manufacturers of those devices would be able to choose their own assessment body. This would level the playing field for all manufacturers (whether they are Australian or based overseas), and would eliminate the current duplication in TGA conducting their own separate conformity assessment review in addition to the equivalent assessment conducted by another qualified and experienced assessment body. It would be important for the TGA to remove itself from providing a conformity assessment service under this proposed model, since it would be a conflict of interest for them to continue this activity, whilst at the same time being involved in the designation of their competitors (see key feature above). It is estimated that this change would result in the 5% of devices required to undergo TGA conformity assessment review, to enter the Australian market in as little as 2-4 weeks (when supported by CE certification from a TGA 'preferred' Notified Body), rather than the 9-24 months currently experienced. A minor change to the regulations would be required to implement this improvement.
4. Regulatory approvals from other jurisdictions to be utilised.	In addition to the generally accepted European CE certification, it is proposed to allow manufacturers to use other equivalent regulatory approvals from recognised competent regulators.

Proposed key features	Differences and advantages
	For example, this could be in the form of: • US FDA Pre-Market Approval (PMA), which is considered to be comparable to the European and Australian Design Examination (DE) review, or • Health Canada product licence. This would not include acceptance of US FDA 510(k) approvals, as they would not be considered equivalent to the Australian regulatory requirements. For example, this would allow sponsors to import certain devices that have approval to be supplied in the US, but that are not supplied in Europe, perhaps because the manufacturer has chosen not to commercialise their product in the EU. The regulations already allow TGA to accept certificates from different jurisdictions as it sees fit, so this improvement would not require any further change to the regulations.
5. The unnecessary 'Manufacturers Evidence' step (2a) to be removed.	The current TGA process (not the regulations) requires the Australian sponsor to first submit a copy of the conformity assessment certification (known as 'Manufacturers Evidence') to the TGA for acceptance before they can use that evidence to support a separate application for entry in the ARTG. Processing times for the Manufacturers Evidence submission vary but can take anywhere from 2 weeks to over a month depending on the workload of TGA at the time. The proposed model eliminates this step and instead replaces it with a requirement to simply attach a copy of the evidence to the application for entry in the ARTG. It is estimated that making this change to the TGA's electronic application process would alone result in a 3-4 week reduction in the time it takes to get a product to market in Australia. As this is only an internal TGA process, no change to the regulations is required to implement this improvement.
6. Fewer devices to be subject to a duplicative product review.	Currently all Class III devices and Active Implantable Medical Devices (AIMD) supported by a European CE certificate must undergo an application audit by TGA (review of product information) regardless of the perceived quality or abilities of the Notified Body that conducted the assessment and issued the certificate. Under the proposed model only those high risk devices supported by CE certification issued by an EU Notified Body that has not been subject to confidence building by TGA would be required to undergo a pre-market application audit. This would in theory provide an incentive for manufacturers to use an EU Notified Body that is preferred by TGA (i.e. TGA has gained and maintains confidence in it). It is estimated that this would result in only 5% of all devices undergoing an application audit prior to entry in the ARTG, compared to approximately 15% currently. Due to the anticipated reduction in workload TGA would be able to conduct fewer application audits in less time than currently,

Proposed key features	Differences and advantages
	thereby improving timely access to medical technology. A minor change to the regulations would be required to implement this improvement.
7. TGA to shift resources from pre-market activities to post-market monitoring and compliance.	Due to the reduction in effort required by TGA during the pre-market assessment phase, the saving in resources could be applied to TGA's post-market activities, such as processing adverse event reports, detecting product failures sooner and enforcing regulatory actions for non-compliance. For a long time MTAA has suggested that TGA operate more like an EU Competent Authority. However, TGA has not been supportive of this suggestion arguing that they would lose the skills and technical knowledge of the employees that currently perform medical device pre-market assessments. MTAA does not believe this is a good reason to regulate in a particular way, as the regulator's resources should be matched to the legislation, rather than the other way around. In any case, MTAA suggests that the skill and technical ability of TGA staff performing pre-market assessment activities could be transferred to post-market monitoring, which requires a strong understanding of the documentary evidence held by manufacturers for the purpose of thorough investigations of adverse events. The added resources in post-market surveillance would increase TGA's ability to conduct adverse event investigations in a timely manner and work with the device sponsor and manufacturer to ensure that if the device is faulty, appropriate corrective actions can be taken. Post-market monitoring is crucial to the safe and effective use of medical devices. Problems appear primarily in relation to sporadic manufacturing issues, which are not apparent or easily detected at the pre-market stage, particularly for implantable devices due to the way they wear over time in the complex environment of the human body. No change to the regulations is required to implement this improvement.
8. TGA to 'licence' Australian sponsors.	Under current regulations, sponsors (suppliers) of medical devices certify that they can obtain evidence of conformity from the manufacturer within 20 days. This requirement means that the sponsor must have an active relationship with the manufacturer of the device. Sponsors are often not aware of their responsibilities under the regulations, including post-market and record keeping responsibilities. This is evident from the reports on TGA's Device Adverse Event Notification (DAEN) database. The relationship of a sponsor with the manufacturer is vital to ensuring that adverse events and complaints are fed back into the design and development process. Under the proposed model TGA would 'license' sponsors to supply medical devices in Australia. The licensing of sponsors would include checks of an active relationship with the manufacturers, and that appropriate systems and resources are in place to meet the ongoing requirements of the regulations (for example, ability to report adverse events

Proposed key features	Differences and advantages
	and adherence to a recognised industry code of practice). Amendments to the regulations would be required to implement this improvement.
9. Improving the visibility of devices in the ARTG.	MTAA has suggested that the way products are entered in the ARTG should be changed to enable easy identification of medical devices currently or previously available for supply in Australia. Amendments to the regulations may be required to implement this improvement.

Staged implementation of the proposed improved system

MTAA acknowledges that many of the proposed improvements to the regulatory system will require legislative changes, international cooperation, and changes to internal TGA processes and IT systems. Therefore, it is proposed that these improvements be rolled out in a staged manner over a period of 2-3 years, rather than trying to make all the changes at the same time. It is proposed that the major changes be made in the following stages:

Stage	Description
1. Remove Regulation 4.1 requiring Australian manufacturers, and certain Class III devices, to obtain TGA Conformity Assessment certification prior to entry in the ARTG.	This could be done immediately, and would still allow manufacturers the option of using the TGA for conformity assessment certification if they did not want to obtain CE certification from an EU Notified Body (for example, small Australian manufacturers who have no interest in supplying their products in the EU). Manufacturers holding TGA conformity assessment certificates could choose to replace this with other CE certification, however this would require any new applications for Class III or AIMD devices to undergo an application audit by TGA prior to entry in the ARTG, as is currently required under Regulation 5.3. MTAA does not believe that there is any need to wait for confidence building activities to be undertaken before this change is implemented, as any high risk devices previously subject to TGA conformity assessment (such as those containing medicines or animal origin materials) will still be reviewed by TGA during a pre-market application audit prior to being included in the ARTG.
2. TGA conducts confidence building activities with EU Notified Bodies and/or EU Competent Authorities to generate a 'preferred' Notified Body list.	This could be achieved through: • the Australia-EU Mutual Recognition Agreement (MRA) which already includes a provision for confidence building, and • TGA's ongoing involvement in the IMDRF Medical Device Single Audit Program (MDSAP). Once complete, TGA could exclude devices from having to be selected for an application audit prior to entry in the ARTG where the manufacturer uses a CE certificate issued by one of the 'preferred' EU Notified Bodies. A minor change to Regulation 5.3 would be required.
3. TGA ceases operating as a Conformity Assessment Body (CAB) and designates third-party CABs to issue Australian CA certificates.	This phase would require additional time to conceive and implement, possibly a period of 2-3 years. During development of this framework TGA would need to be able to maintain their own CA certification services until enough CABs have been designated and Australian manufacturers have arranged to transfer their certification to one of the new CABs.

SWOT analysis of the proposed improved regulatory system

Strengths	Weaknesses
• Greater confidence in the abilities of conformity assessment bodies. • Greater confidence that sponsors are meeting their regulatory obligations. • Reducing red tape without reducing patient safety. • Faster access to medical technology. • The designation model would suit the needs of NZ under ANZTPA. NZ industry has voiced concerns about the TGA premarket approval process.	• Public and political perception that the regulator has less control. • Retraining of regulator and industry staff
Opportunities	**Threats**
• Best practice regulation through ANZTPA. • Increase resources in post-market activities will increase the regulator's reaction time, improving patient safety. • Increase resource in post-market activities will support the ability of the regulator to report to other sectors of health care on medical device use issues to encourage the quality use of devices. • Local conformity assessment body expertise will create jobs. • Local manufacturer access to conformity assessment bodies that assess products for other jurisdictions and introducing them to the requirements of other countries. • Sponsor licensing.	• Consumer concerns. • Political environment. • Significant redrafting of legislation (ANZTPA).

Risk mitigation

Risk	Mitigation action
Public and political perception that the regulator has less control.	Public and political education of the system with respect to the designation of conformity assessment bodies and licensing of sponsors, and transparency of this process. Increase post-market activities and advice to the healthcare system from the regulator will give greater confidence that the most efficient actions to protect patients are being taken.
Retraining of regulator and industry staff	As both TGA and industry staff has good knowledge of regulatory requirements, retraining in new or expanded roles should not be a major issue.
Consumer concerns and political environment	Public transparency of the system with respect to designation of conformity assessment bodies and licensing of responsible sponsors.
Significant redrafting of legislation	Redrafting of regulations will be required with ANZTPA – the joint agency is an opportunity to get things right.

7. Conclusions

MTAA is able to provide many specific examples of red tape in the current medical device regulatory system, many of these examples have been previously tabled with TGA through consultations and regulatory forums.

As described in MTAA's response to TGA's recent Regulation Impact Statement (RIS) for changes to pre-market assessment, the proposed additional pre-market requirements for high risk devices will not prevent another high profile device failure, such as PIP breast implant or ASR hip replacement issues. It is the TGA's ability to analyse, trend and react to post-market feedback quickly that will ultimately improve patient safety.

The designation and ongoing monitoring of conformity assessment bodies will provide much greater confidence that thorough assessments of medical devices are conducted by people with appropriate qualifications and expertise.

The licensing of sponsors will provide the regulator with confidence that sponsors are capable of supplying medical devices to the Australian market, and are aware of their ongoing regulatory obligations throughout the product lifecycle.

MTAA believes the proposed changes outlined in this paper will improve TGA's efficiency and value for money, result in significant cost savings for Australian businesses and, most importantly, improve health outcomes for Australian patients.