Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Reforms in the Medical Devices Regulatory Framework: Summary Table of Submissions

Relevant industry sectors, professional and consumer groups, and individuals provided comment and input to the proposals outlined in the discussion paper *Reforms in the Medical Devices Regulatory Framework*. A summary table has been compiled and is available below.

The submissions received by the TGA are listed in alphabetical order of name of organisation. Please note that submission 70 was not included by request of the submitting organisation.

Summary Table of Comments Received

Proposal 1	**1 Reclassification of joint replacement implants.** That a new classification rule be added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder- joint replacement implants from Class IIb to Class III medical devices.
Proposal 2	**2A Use of third party assessment bodies for Australian manufacturers.** That Subregulation 4.1(1) be removed from the medical device Regulations so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.
	2B Increasing pre-market scrutiny for implantable medical devices: **(i) Devices requiring a TGA Conformity Assessment Certificate to be issued; and** That Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices. **(ii) Applications to be selected for auditing.** That Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.
	2C Recognition of third party assessment bodies: **(i) Confidence building for EU Notified Bodies designated under the MRA; and** That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

	(ii) Recognising Australian third party assessment bodies. That further consultation be undertaken to investigate the development of a system whereby Australian-based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.
Proposal 3	**3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices:** **(i) amend the way in which a kind of device is included on the ARTG**; and **(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.**
Proposal 4	**4 Publication of device product information on the TGA Website.**

Proposal 1

#	Respondent	Response
1	3M Australia Pty Ltd	No comment
2	Abbott Australasia P/L (Diagnostics Division)	No comment
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	No comment
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position
5	Amgen Australia	No comment
6	AMPAC Dental Pty Ltd	No comment
7	ANZ dental	No comment
8	AusBiotech Ltd	Supports but suggests holding off on partial joints until the European Union Commission implements extensively and additional evidence and data can confirm that such reclassification will indeed improve patient outcomes. Suggest that the NJRR data is further analysed to allow for age and other factors that may influence relative risk before implementing changes to reclassify partial joints.
9	Australian Dental Association Inc	No comment.

	(ADA)	
10	Australian Dental Industry Association Inc (ADIA)	Supported.
11	Australian Health Insurance Association (AHIA)	Supported, with expanded scope of devices to include spinal prostheses and ensuring a strict two-year transition period.
12	Australian Orthopaedic Association Limited	Supported. Believes that this reclassification will bring with it an increased assessment process of clinical evidence and recommends that an overarching committee be formed to review the applications in a timely manner. Should consist of key stakeholder groups- government, the clinical colleges, medical device and technology groups. Recommends the chair to be a suitably qualified clinician with nationally recognised clinical and managerial skills. Recommends a reduction in the transition period to six-to-twelve months to avoid Australia becoming a repository for unacceptable implants from overseas and that a clinical review of all applications is undertaken once the date of change is announced.
13	Baxter Healthcare Pty Limited	No comment.
14	BIOTRONIK Australia Pty Ltd	No comment.
15	BORG Dental (Bordent Pty Ltd)	No comment.
16	Bosco Medical Australia	No comment.
17	Bourke Dental Supplies	No comment.
18	CareFusion Australia & New Zealand	No comment.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	No comment.
21	Consumers Health Forum of Australia (CHF)	Supported.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	No comment.
24	Dentalife Pty Ltd	No comment.

25	Dentaurum Australia Pty Limited Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Not relevant so no comment.
27	Department of Innovation, Industry, Science and Research	Concerned at any increase in regulation without demonstrated safety issues, which is at odds with the HTA review. This proposal appears to be supported by evidence from the National Joint Replacement Register.
28	Device Technologies Australia Pty Ltd	Does not support. Current post market surveillance is proving effective. Increasing the classification will not facilitate access to new improved technologies. If it proceeds propose an exemption for non-transitioned joint replacement components for revision only be applied and annual fees and application audit fees are waived for joint replacement implants during the transition period.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	No comment.
31	EBR Regulatory Affairs Consultants	This should be done product by product. Identify the root cause of the revisions being higher for total joints i.e. some patients should never have been given a total hip in the first place or is it surgical skill. TGA should guarantee that this will not affect turnaround time for reviews and need further clarification exactly how this will level the playing field.
32	Erskine Dental	No comment.
33	Essology Pty Ltd	No comment.
34	Fisher & Paykel Healthcare Limited	No comment.
35	GE Health Care Australia Pty Ltd	No comment.
36	GlaxoSmithKline Australia Pty Ltd	No comment.
37	Gunz Dental Pty Ltd	No comment.
38	Healthlinks.net Pty Ltd	No comment.
39	Henry Schein Halas	Supported.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment.
41	Integra Neurosciences Pty Ltd	No comment.

42	Invacare Australia Pty Ltd	No comment.
43	IVD Australia	No comment.
44	Ivoclar Vivadent Pty Ltd	No comment.
45	Johnson & Johnson Medical Pty Ltd	Supported but requests that the proposed two-year transition period be increased to a minimum of four years. Would like further clarification of the unique product identifiers requirement for orthopaedic implants.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment.
47	Magic Mobility (Red Milawa Pty Ltd)	No comment.
48	MAQUET Australia Pty Ltd	Change does not affect MAQUET Australia. Comment that the majority of sponsors have agreements set for 5 years to supply at contractually agreed pricing. Any of these changes will need to be absorbed by the sponsors.
49	Max Boccardo Associates	Supported. Suggests that Class IIb devices be reclassified as Class IIa.
50	Medical Technology Association of Australia (MTAA)	Recommends that: • Reclassification of Class IIb implantable orthopaedic joints as Class III devices be undertaken with a Level-2 application audit and then a TGA conformity assessment certificate be issued following review of the design certificate; • TGA quarantine components of superseded implantable systems retained for revision or repair procedures and accept Class IIb level certification; • Alignment of transition periods with a four year transition for the reclassification of implantable orthopaedic joints; and • A staged implementation of reclassification, starting with full joints then moving to partial joints at a later date.
51	Medtronic Australasia Pty Ltd	Supported. TGA needs to be aware of the increased workload and could offset this by using designated Australian Conformity Assessment Bodies.
52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	No comment.

55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Supported but suggests that devices already on the ARTG be 'grandfathered' rather than having to resubmit applications. Has implications regarding Proposal 2B.
57	Otto Bock Australia Pty Ltd	No comment.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Support total implants. Suggest that Europe does not include partial implants and including them will be contrary to the GHTF and harmonisation. Other national joint registers have not seen similar issues to that of the National Joint Replacement Registry report which lacks some key parameters of assessment that would enable the TGA to justify an up classification of partial joint replacements. Concerned that the supply of revision components for older joint systems remains unaddressed in this proposal. Use of the Special Access Scheme will result in the denial of reimbursement and will disadvantage the patient financially and may lead to this no longer being an option. Note that an existing Class IIb entry will lead to multiple Class III applications because of the UPIs. Unclear if ARTG number for an existing Class IIb inclusion can still be referenced for reimbursement until the transition process is complete? TGA has not indicated how long the reclassification will take creating uncertainty for the market. Suggest treat existing Class IIbs as an up classification rather than a new application and only require a Level 2 application audit.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	Questions the risk of omitting ancillary components from the higher classification leading to higher ongoing revision rates.
61	Queensland Health– Chief Health Officer	Support. Although concerns raised that there is assurance that the implant and related items are recognised as a complete related set or system.
62	Queensland Health– Centre for Healthcare Improvement	No comment.
63	Resmed	Not applicable.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	No comment.

66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Supports provided it matches the EU system. The additional cost to industry requires further consultation.
68	Stryker Australia	TGA consult with industry to add additional variants to the current approval list and provide greater flexibility in the selection of UPIs. Allows same level of visibility and reduces the number of applications assessed by the TGA reducing costs and resource requirements of the TGA. An extended transition period for partial joint replacement implants to allow manufacturers to work with the notified body and obtain the necessary documents. Recommend that the SAS be redesigned to a notification based model similar to that for custom made implants to cope with the increases.
69	STS Health	No comment.
70	N/A	N/A
71	The Pharmacy Guild of Australia	No comment.
72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Recommend that partial joint implants be removed from the proposal as the EU MDD can be interpreted to allow IIb classification for partial joint prosthesis which may mean some devices classified IIb in Europe will require a higher classification in Australia. Recommend the same 5 year phase in that Europe had as two years is too short considering that manufacturers must collate evidentiary data to demonstrate safety, quality and performance of the affected implants. Propose a risk managed approach to the transitioning of implants. The longer they have been on the market the less clinical evidence required. Concerned at the use of the Special Access Scheme and the loss of reimbursement. Recommend a guidance document is developed with input from all stakeholders prior to implementation. Concerned at resource implications for the TGA having flow on effects with new application processing.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 2

Proposal 2A

#	Respondent	Response
1	3M Australia Pty Ltd	No effect on business, however supports
2	Abbott Australasia P/L (Diagnostics Division)	Whilst not an Australian manufacturer of IVDs supports this proposal.
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	Support- with the certification of these assessment bodies to be undertaken by the National Association of Testing Authority (NATA).
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position
5	Amgen Australia	Supports
6	AMPAC Dental Pty Ltd	No comment
7	ANZ dental	No comment
8	AusBiotech Ltd	Support however have concerns that linking this proposal with 2B and 2C would result in additional delays and that concessions granted in 2A would be nullified in 2B for some products.
9	Australian Dental Association Inc (ADA)	No comment.
10	Australian Dental Industry Association Inc (ADIA)	Minimal impact on the Australian dental industry, however support.
11	Australian Health Insurance Association (AHIA)	Support- Ensure alignment of risk stratification rules with Australia and robust implementation of proposal 2C (i).
12	Australian Orthopaedic Association Limited	No comment.
13	Baxter Healthcare Pty Limited	No comment.
14	BIOTRONIK Australia Pty Ltd	No comment

15	BORG Dental (Bordent Pty Ltd)	No comment
16	Bosco Medical Australia	No comment
17	Bourke Dental Supplies	No comment
18	CareFusion Australia & New Zealand	This is a positive initiative.
19	Carl Zeiss Vision	No comment
20	ConMed Corporation	No comment
21	Consumers Health Forum of Australia (CHF)	Supports the whole proposal as long as they are taken together.
22	Cosmetic Physicians Society of Australasia Inc	No comment
23	Critical Dental Pty Limited	No comment
24	Dentalife Pty Ltd	No comment.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Not relevant directly but support.
27	Department of Innovation, Industry, Science and Research	Strongly supports. While the approach will have positive impacts much will depend on the coverage of the proposed change and the effect of the proposed change, if the TGA will accept certificates for all classes of device.
28	Device Technologies Australia Pty Ltd	Supports and considers that this can be implemented irrespective of Proposal 2B.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	Concerned that any concessions in Proposal 2A are nullified by Proposal 2B. Proposal 2B appears to withdraw the possibility of utilising CE certification to support their ARTG entry for Class IIb and Class III products.
31	EBR Regulatory Affairs Consultants	TGA should guarantee that this will not affect turnaround time for reviews. The confidence building period should be short. Are there costs associated with being on the MRA list? The recognition of third party assessments is taking too long. It is not clear if the TGA has a role in designating CABs via the MRA. Under what circumstances will the TGA refuse supply if the MRA is used?

32	Erskine Dental	Little impact but support the change.
33	Essology Pty Ltd	No comment
34	Fisher & Paykel Healthcare Limited	No comment
35	GE Health Care Australia Pty Ltd	No comment
36	GlaxoSmithKline Australia Pty Ltd	No comment
37	Gunz Dental Pty Ltd	No comment
38	Healthlinks.net Pty Ltd	No comment
39	Henry Schein Halas	Minimal impact on the Australian dental industry, however support.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment
41	Integra Neurosciences Pty Ltd	No comment
42	Invacare Australia Pty Ltd	No comment
43	IVD Australia	Supportive.
44	Ivoclar Vivadent Pty Ltd	No comment
45	Johnson & Johnson Medical Pty Ltd	Support.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment
47	Magic Mobility (Red Milawa Pty Ltd)	No comment
48	MAQUET Australia Pty Ltd	No comment
49	Max Boccardo Associates	Support. Proposal 2A and 2C(ii) should be treated as one.
50	Medical Technology Association of Australia (MTAA)	Supports.
51	Medtronic Australasia Pty Ltd	Support- but TGA needs to ensure that the timing of this coincides with the approval or designation of Conformity Assessment Bodies operating in Australia to prevent the situation of manufacturers choosing a Conformity Assessment Body that is later not approved.

52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	Accepting conformity assessment from third parties (particularly Europe) is inconsistent with Recommendation 8 (c) of the HTA review. Suggest that the quality of information provided by the European Notified Bodies be improved dramatically, standardised and monitored before they could be of use to Australia.
54	Nobel Biocare Australia Pty Ltd	No comment.
55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Support. Removes the disparity between Australian and overseas manufacturers.
57	Otto Bock Australia Pty Ltd	No comment
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Supports. Unclear who will be responsible for the appointment of third party CABs.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	Questions the requirements of the quality standards of third party assessors. Also unclear as to which authority will regulate these third parties or how third parties will guarantee quality of product.
61	Queensland Health– Chief Health Officer	Support.
62	Queensland Health– Centre for Healthcare Improvement	No comment
63	Resmed	Support. The current approach is burdensome on Resmed and similar Australian manufacturers that distribute locally and overseas.
64	Royal Australasian College of Physicians (RACP)	No comment
65	RTI Biologics Inc	No comment
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Broadly supports but seeks further details on the recognition of third party assessment bodies.
68	Stryker Australia	Supports.

69	STS Health	No comment.
70	N/A	N/A
71	The Pharmacy Guild of Australia	No comment.
72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Support.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 2B(i)

#	Respondent	Response
1	3M Australia Pty Ltd	No comment
2	Abbott Australasia P/L (Diagnostics Division)	No comment
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	No comment
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position
5	Amgen Australia	No comment
6	AMPAC Dental Pty Ltd	No comment
7	ANZ dental	No comment
8	AusBiotech Ltd	Does not support due to the potentially enormous increase in regulatory burden. The discussion paper and the review do not provide evidence of regulatory failure in higher risk devices. Doubts if the TGA will have sufficient resources to undertake the increase in assessments leading to market delays. The potential burden of

		increased fees per device is estimated to be 8 fold for Class III and AIMD implants. It is also unclear if some approved products will be covered by 2B or whether they can be accepted using CE Mark certification as in 2A and which mechanisms will be implemented to avoid a second round of change for joint implants.
9	Australian Dental Association Inc (ADA)	No comment.
10	Australian Dental Industry Association Inc (ADIA)	Minimal impact on the Australian dental industry, however support.
11	Australian Health Insurance Association (AHIA)	Support- Periodic reviews should also align with private health concerns as a number of devices and procedures occur primarily in this setting. Include spinal prostheses as Class III devices.
12	Australian Orthopaedic Association Limited	Supports prostheses issued with an EC certificate or equivalent from an overseas regulatory body requiring confirmation of the data provided, by a clinical advisory body. Agrees with a transition period however suggests a reduction to six to twelve months and suggests clinical advisory body review of all applications once the date of change is announced to avoid the supply of joint implants into Australia that are unacceptable in other countries and Europe. Also suggest that variations must initiate New Application status in order to capture 'look alike 'prostheses as prostheses come off patent.
13	Baxter Healthcare Pty Limited	Support for new implantable devices seeking registration. The cost for requiring existing implantable devices would be a heavy burden.
14	BIOTRONIK Australia Pty Ltd	Suggests that proposal 2B(i) be amended to require a TGA conformity assessment certificate to also be issued for all Class III/AIMD intended for long term use unless their conformity assessment has been assessed by a Notified Body which has been approved for the purpose of the European Community Mutual Recognition Agreement. Changes would lead to approx3.5 million dollars in extra cost to BIOTRONIK AUSTRALIA PTY LTD given the majority of their devices are Class III and AIMDs. Also question the TGA's ability to source enough staff to clear the back log. Suggest applying a transition period of four years after the commencement of the new regulations to new products intended for introduction to the market.
15	BORG Dental (Bordent Pty Ltd)	Do not support. Will have significant impact on the dental industry. Impost of an audit cost will impact on the viability of the devices, restrict range, availability and promotional viability and lead to increased costs to the consumer.

16	Bosco Medical Australia	No comment
17	Bourke Dental Supplies	Do not support. Significant impact on the dental industry leading to increased costs to professionals and consumers. Restrict the range, availability and promotional viability.
18	CareFusion Australia & New Zealand	This is a positive initiative.
19	Carl Zeiss Vision	No comment
20	ConMed Corporation	This would be cost prohibitive, especially if site visits were required at manufacturing facilities in Europe and the USA. Requires further clarification of the TGA's extent of this proposal, including full assessment fees. Questions if TGA has enough resourcing to undertake this leading to further delays and costs for new products with possible establishment of an assessor base for similar to the NB competence levels the proposal is trying to overcome. Additional cost, resource and time burden would discourage new and existing applications. Costs to ConMed Corporation based on current Class III inclusions > $1,000,000 which includes TGA CA Fees and Charges, TGA travel costs, surveillance costs (5 years), and design examination fees and charges. Suggest minimum 12 month transition.
21	Consumers Health Forum of Australia (CHF)	Welcomes improvements to implant classification. Support provided all of proposal 2 goes forward.
22	Cosmetic Physicians Society of Australasia Inc	Would like to see the scope expanded to include IPL and laser machines. Also suggest that the TGA work with Government through the COAG process to establish a national regulatory framework for the use of IPLs and laser machines.
23	Critical Dental Pty Limited	No comment
24	Dentalife Pty Ltd	No comment.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Supports the change subject to this only applying to medical devices covered by classification rules 3.4, 5.2, 5.7, and 5.9. Any others should be subject to further consultation.
27	Department of Innovation, Industry, Science and Research	Concerned at any increase in regulation without demonstrated safety issues which is at odds with the HTA review.
28	Device Technologies Australia Pty Ltd	Does not support. Proposes that a third level of medical device application audit be created specifically to address the additional assessment requirements for Class III and AIMDs. If this proposal proceeds then suggest that the

		following are developed and published prior to implementation: scheduled reduced fees for conformity assessment; TGA's business rules regarding abridgements and reductions of CA fees and assessments; and the rules for selection and on-site manufacturer facility audits. Suggest all conformity assessment application and assessment fees (including onsite audits) are reduced on a sliding scale, with the greatest reduction earlier in the transition period; and any surveillance or other associated fees incurred during the transition period are reduced.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	It is unclear if Dynek's products fall within the sphere of Proposal 2B. Or whether they will be accepted onto the ARTG using the CE Mark certification, in accordance with Proposal 2A. Currently pay for SGS certification and surveillance audits and the TGA's duplication of the same activities plus will have to pay "Application Audit Fees" for four Class IIb products adding between $12,000 and $22,640 to the regulatory costs.
31	EBR Regulatory Affairs Consultants	TGA should guarantee that this will not affect turnaround time for reviews.
32	Erskine Dental	No comment.
33	Essology Pty Ltd	No comment
34	Fisher & Paykel Healthcare Limited	No comment
35	GE Health Care Australia Pty Ltd	No comment
36	GlaxoSmithKline Australia Pty Ltd	No comment
37	Gunz Dental Pty Ltd	No comment
38	Healthlinks.net Pty Ltd	No comment
39	Henry Schein Halas	Minimal impact on the Australian dental industry, however support.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment
41	Integra Neurosciences Pty Ltd	Require a longer implementation period- minimum 2 years. Would require more consultation and would like to know the costs involved. Need further evidence that this provides a sound evidence basis for the Commonwealth HTA process.
42	Invacare Australia Pty Ltd	No comment
43	IVD Australia	No comment

44	Ivoclar Vivadent Pty Ltd	No comment
45	Johnson & Johnson Medical Pty Ltd	Agrees that increased scrutiny is appropriate for Class IIb, Class III and AIMD devices. However this should not require the introduction of level 2 application audits and TGA conformity assessment certificates. Increased oversight of international agencies and acceptance of certification from those demonstrating high standards would serve the same purpose. Concerned at the increase in resources that the TGA will require particularly when coupled with proposal 1. Concerned at the increase in fees. Propose that the TGA should: adopt the role of a designating authority for international and domestic Conformity Assessment Bodies which can demonstrate competence to evaluate all medical devices requiring pre market assessment for supply in Australia; extend the confidence building measures of Proposal 2 (c)i to include a subset of Notified Bodies from which CE certification can be accepted instead of TGA conformity assessment; continue to emphasise and maintain a robust post-market surveillance system; and proceed to full acceptance of third party conformity assessment as the basis for ARTG inclusion.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment
47	Magic Mobility (Red Milawa Pty Ltd)	No comment
48	MAQUET Australia Pty Ltd	Change does not affect MAQUET Australia. Comment that the majority of sponsors have agreements set for 5 years to supply at contractually agreed pricing. Any of these changes will need to be absorbed by the sponsors.
49	Max Boccardo Associates	Support.
50	Medical Technology Association of Australia (MTAA)	Recommends that TGA issue a conformity assessment certificate on the basis of a Level 2 application audit and review of a design examination report.
51	Medtronic Australasia Pty Ltd	This proposal will require an additional $12.5 million in re-registration costs for Medtronic Australasia Pty Ltd to have products already on the ARTG go through a new conformity assessment. These products have already gone through a level 2 application audit and have conformity assessment evidence from a notified body. No evidence to suggest a level 2 application audit has failed to stop unsafe devices entering the market. Propose: • The TGA continues with Level 2 application audits for all implantable class III and AIMDs but condition of inclusion on the ARTG is the issue of a Certificate of Review which expires after 5 years and requires the TGA to do an application review, including: • Updated design examination (Annex II-4) certificate and design; • Risk management file; and • Clinical evaluation;

		• Or Abridged conformity assessment should the TGA proceed and that the TGA consider conformity assessments from other GHTF members such as PMA Approval USA and Health Canada.
52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	No comment.
55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Does not support. This will result in additional fees and longer approval times. Would require evidence to support that the current approval process has resulted in adverse performance and/or safety outcomes for patients. This reform introduces duplication of regulatory authority assessments. If it does proceed then recommends a grandfather clause.
57	Otto Bock Australia Pty Ltd	No comment
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Supports for all new products. Suggest that all Class III products which have already undergone a Level 2 audit should not be subject to a new conformity assessment audit as the relevant data has already been assessed by the TGA. These products should automatically receive a conformity assessment certificate for the existing products and if necessary only need to provide the latest Notified Body report, updated risk and clinical evidence reports. Requiring further information will significantly increase TGA's workload and cause delays in the assessment. Transition period of 4 years is acceptable for existing Class III devices. The consultation paper did not identify the periodic review or renewal period to be applied to the Conformity Assessment Certificate and how it will be assessed.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	No comment.
61	Queensland Health– Chief Health Officer	Support.
62	Queensland Health– Centre for Healthcare Improvement	No comment.

63	Resmed	No comment as it is not applicable if the proposal is restricted to implantable medical devices.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	No comment.
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Does not support. TGA should explore ways to streamline the existing assessment system particularly for products that already have CE marks. Current approval times and processes are too onerous and replicate assessment carried out by the EU notified body resulting in significant delays. The TGA could refocus its role to verification of the EU assessment by way of Application Audit and review of the EU design examination report.
68	Stryker Australia	Difficult to justify that all new and old devices undergo a separate additional Conformity Assessment so that the TGA can issue independent certification. Recommend that the TGA request additional information during the application assessment. The increased workload to the TGA would increase approval times causing delays to market. Recommend not requiring a conformity assessment certificate for any of the devices captured under proposal 1 instead require them to undergo a Level 2 application audit and a review of the summary technical file.
69	STS Health	No comment.
70	N/A	N/A
71	The Pharmacy Guild of Australia	No comment.
72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Requires renewal of existing ARTG entries. Concerned applications for new products will be held up during the transition process. Propose TGA consider a risk management approach and review only higher risk devices and novel/innovative products. Propose considering an abridged Conformity Assessment Route and Full Conformity Assessment Route such as in Singapore.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 2B(ii)

#	Respondent	Response
1	3M Australia Pty Ltd	Suggest that the TGA further revise their internal evaluation process for Class iib applications rather than applying application audit. • All the required documentation for application audit would already be part of the submission and no need to apply application audit for class IIb implantables; • Proposal will significantly increase cost –Class IIb application fee is $810, application audit will increase cost to $5650; • In association with Proposal 3 every new device will undergo an application audit; and • Increased market authorisation period.
2	Abbott Australasia P/L (Diagnostics Division)	No comment
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	No comment
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position
5	Amgen Australia	No comment.
6	AMPAC Dental Pty Ltd	No comment.
7	ANZ dental	No comment.
8	AusBiotech Ltd	Does not support due to the potentially enormous increase in regulatory burden. This proposal should also include provisions for mandatory timeframes for companies to plan product introductions more effectively.
9	Australian Dental Association Inc (ADA)	Not supported. Likely to have a negative impact on access to dental implants.
10	Australian Dental Industry Association Inc (ADIA)	Not supported. Suggest that a risk management approach be taken where application audits are only required for types of medical devices where safety performance issues arise and that the TGA engage in further discussions to define what safety or performance issues may require an application audit.
11	Australian Health Insurance	Support- ensure intra-ocular visco-elastic fluids are inclusive of liquids and gases. Would like to see included all

	Association (AHIA)	device accessories integral to the operation of an Intermittent Pulse Generator in either a coronary, spinal or neural setting.
12	Australian Orthapaedic Associaiton Limited	See 2B (i).
13	Baxter Healthcare Pty Limited	Support for new implantable devices seeking registration. The cost for requiring existing implantable devices would be a heavy burden.
14	BIOTRONIK Australia Pty Ltd	Generally support this proposal however question the ability of the TGA to handle the increased workload.
15	BORG Dental (Bordent Pty Ltd)	Do not support. Will have significant impact on the dental industry. Impost of an audit cost will impact on the viability of the devices, restrict range, availability and promotional viability and lead to increased costs to the consumer.
16	Bosco Medical Australia	No comment.
17	Bourke Dental Supplies	Do not support. Significant impact on the dental industry leading to increased costs to professionals and consumers. Restrict the range, availability and promotional viability.
18	CareFusion Australia & New Zealand	This is a positive initiative.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	Similarly lead to increased regulatory cost, burden and delays similar to 2B (i).
21	Consumers Health Forum of Australia (CHF)	Welcomes improvements to implant classification. Support provided all of proposal 2 goes forward.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	No comment.
24	Dentalife Pty Ltd	No comment.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Under the current fee structure this would increase costs from $810 to approximately $4000 for each approval leading to increased costs for consumers. Does not support unless dental implants are excluded. Would prefer to adopt regular reviews of devices to undergo an application audit and only add dental devices if safety or

		performance issues arise.
27	Department of Innovation, Industry, Science and Research	Concerned at any increase in regulation without demonstrated safety issues which is at odds with the HTA review.
28	Device Technologies Australia Pty Ltd	Does not support due to lack of detail. If this proposal proceeds then suggest that the TGA implement methods to ensure faster processing times for level two application audits and a significant fee reduction following a comprehensive cost impact survey.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	See comments for Proposal 2B (ii).
31	EBR Regulatory Affairs Consultants	TGA should guarantee that this will not affect turnaround time for reviews.
32	Erskine Dental	Support in principle.
33	Essology Pty Ltd	No comment.
34	Fisher & Paykel Healthcare Limited	No comment.
35	GE Health Care Australia Pty Ltd	No comment.
36	GlaxoSmithKline Australia Pty Ltd	No comment.
37	Gunz Dental Pty Ltd	This will have an impact on the import of Maxillo-Facial implants. Increased audit costs will impact on the viability, range, availability promotional viability and increase cost to market and the patient.
38	Healthlinks.net Pty Ltd	No comment.
39	Henry Schein Halas	Not supported. Suggest that a risk management approach be taken where application audits are only required for types of medical devices where safety performance issues arise and that the TGA engage in further discussions to define what safety or performance issues may require an application audit.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment.
41	Integra Neurosciences Pty Ltd	Require a longer implementation period- minimum 2 years. Would require more consultation and would like to know the costs involved. Need further evidence that this provides a sound evidence basis for the Commonwealth HTA process.
42	Invacare Australia Pty Ltd	No comment.

43	IVD Australia	No comment.
44	Ivoclar Vivadent Pty Ltd	No comment.
45	Johnson & Johnson Medical Pty Ltd	Agrees that increased scrutiny is appropriate for Class IIb, Class III and AIMD devices. However this should not require the introduction of level 2 application audits and TGA conformity assessment certificates. Increased oversight of international agencies and acceptance of certification from those demonstrating high standards would serve the same purpose.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment.
47	Magic Mobility (Red Milawa Pty Ltd)	No comment.
48	MAQUET Australia Pty Ltd	Dependent upon the level of fees this could drastically limit new products coming to market. Suggest the TGA limit fees to well below current level 2 application audit fee of $5650.
49	Max Boccardo Associates	Support.
50	Medical Technology Association of Australia (MTAA)	Recommends: • expanding the current application audits to include products approved by Health Canada and US FDA as the basis for an entry in the ARTG; and • implementing a statutory timeframe.
51	Medtronic Australasia Pty Ltd	Proposes an application audit which comprises: • Australian Declaration of Conformity; • IFU/labels; • Risk management file; and • Clinical evidence supplied for CE marking. Variations to Class IIb should be by notification as proposed in 3 (i).
52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	This will have an impact on the availability of new medical devices resulting in delays to patients. Propose that the review be limited to safety and performance of the device as in the US or allow a manufacturer to declare conformance to essential principles like the EU system. The EU only requires an application audit for new

		products Class II and above or if the new product range would fall outside of the approved manufacturing scope of a given company granted by the Notified body (EC licence). Welcomes a continued MRA system for Class IIb and encourages the concept of qualifying individual notified bodies as capable of mutual recognition through confidence building.
55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Does not support without supporting evidence to justify additional fees and longer approval times.
57	Otto Bock Australia Pty Ltd	No comment.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Inconsistent with the agreed GHTF classification rules. No demonstrated increase in risk to reclassify these products. Will lead to higher compliance costs. Suggest that this change only apply to new inclusions.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	No comment.
61	Queensland Health– Chief Health Officer	Support.
62	Queensland Health– Centre for Healthcare Improvement	No comment.
63	Resmed	Support. The current approach is burdensome on Resmed and similar Australian manufacturers that distribute locally and overseas.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	No comment.
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Does not support. In the spirit of harmonisation, TGA should accept evidence of CE marking as suitable evidence for entry to the Australian market.
68	Stryker Australia	Understands the perceived need.
69	STS Health	No comment.

70	N/A	N/A
71	The Pharmacy Guild of Australia	No comment.
72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Support for new applications but propose TGA accept the EU notified Bodies Design Examination Certificates for existing devices.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 2C(i)

#	Respondent	Response
1	3M Australia Pty Ltd	Support the proposal.
2	Abbott Australasia P/L (Diagnostics Division)	Supports although recommends that any inclusion of IVDs in the MRA not be undertaken until after the EU commission review is complete (approx 2015). Does not support the option whereby only certificates issued by MRA notified bodies are accepted as Manufacturers Evidence nor that certification issued by non-MRA Notified Bodies undergo application audits. Does not align with global harmonisation nor is the level of risk commensurate with the level of regulatory oversight.
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	No comment.
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position.
5	AMPAC Dental Pty Ltd	No comment.
6	Amgen Australia	No comment.

7	ANZ dental	No comment.
8	AusBiotech Ltd	Support. Recognises that the competence of Notified Bodies is critical and should be subject to rigorous assessment and supervision. Notes that the TGA already has several years experience with the medical devices regulatory framework, based on the GHTF model and could use this accumulated experience to shorten the timeframe for confidence building as well as consider the proposal to include notified bodies that the TGA accepts CE certification from as equivalent to TGA conformity assessment. Propose the TGA start with a subset of notified bodies already recognised under the MRA and seek further advice from the European competent authorities and industry to identify those most acceptable. Industry expects this reform to be implemented quickly.
9	Australian Dental Association Inc (ADA)	Support but with the qualification that this process conducted after a cost benefit study has been undertaken and proper project management principles are in place so that the TGA's financial commitment is not open ended.
10	Australian Dental Industry Association Inc (ADIA)	Unsure of the impact on the Australian dental industry however support.
11	Australian Health Insurance Association (AHIA)	Support.
12	Australian Orthopaedic Association Limited	No comment.
13	Baxter Healthcare Pty Limited	No comment.
14	BIOTRONIK Australia Pty Ltd	Fully supports.
15	BORG Dental (Bordent Pty Ltd)	Unclear on the constructive reason for this proposal.
16	Bosco Medical Australia	No comment.
17	Bourke Dental Supplies	This proposal has implications internationally with the issuing of CE certificates from manufacturers. If the international companies have not had a CE certificate issued by an MRA authorised certification body we are quite unclear on the constructive reason for this proposal.
18	CareFusion Australia & New Zealand	This is a positive initiative.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	Suggest TGA designate a reduced number of reputable NB accredited to issue EC Certificates and publish on website in addition or alternately initially recognise EC certificates issued by currently designated MRA NB

		until others become accredited.
21	Consumers Health Forum of Australia (CHF)	Support provided all of proposal 2 goes forward.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	No comment.
24	Dentalife Pty Ltd	No comment.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Will be important to clearly define the financial commitment required by both the TGA and the EC as part of the project management and to consult further with industry on how the financial commitment of the TGA will be funded.
27	Department of Innovation, Industry, Science and Research	Have some implementation concerns. If the TGA develops and publishes criteria for appropriate third party conformity assessment for use in future bilateral agreements and to be used for recognising Australian third party assessment bodies in Proposal 2C (ii) this is likely to increase confidence in notified bodies that conform with the criteria.
28	Device Technologies Australia Pty Ltd	Supports in principle. Does not support to only accept CE certificates from MRA notified bodies as manufacturer's evidence. Propose that a definition and route for gaining designation as an MRA notified body is developed. Does not support the requirement that all applications supported by non-MRA notified bodies undergo a mandatory application audit.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	Proposal 2C (i) is unjust and inconsistent. Dynek's understanding of the EU MRA is that the TGA is regarded as if it were another EU competent Authority and the MHRA has adequate confidence in any European Competent Authority for access to the UK market for CE marked devices but the TGA does not have the same reciprocal confidence.
31	EBR Regulatory Affairs Consultants	The confidence building period should be short. Are there costs with being on the MRA list? Under what circumstances will the TGA refuse supply if the MRA is used?
32	Erskine Dental	Strongly support but need to monitor to ensure cost effectiveness and financial commitment is not over extended.

33	Essology Pty Ltd	No comment.
34	Fisher & Paykel Healthcare Limited	No comment.
35	GE Health Care Australia Pty Ltd	No comment.
36	GlaxoSmithKline Australia Pty Ltd	No comment.
37	Gunz Dental Pty Ltd	Implications for Gunz Dental Pty Ltd if international companies that have not had CE certificate issued by an MRA authorised certification body. Unclear on the constructive reason for the proposal. Concerns with why an MRA needs to be established and that TGA's financial commitment may be an open ended one.
38	Healthlinks.net Pty Ltd	No comment.
39	Henry Schein Halas	Unsure of the impact on the Australian dental industry however support.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment.
41	Integra Neurosciences Pty Ltd	Suggest undertaking this before implementing 2B. Suggest that CMDCAS QS certificates and Health Canada Product Licences where the device is equivalent be used. Also consider that certification issued by MRA notified bodies be acceptable for application audits whether the device has been manufactured in the EU or not.
42	Invacare Australia Pty Ltd	No comment.
43	IVD Australia	Is supportive but does not support the option that TGA give greater weight to EC certificates issued by notified bodies that have undergone confidence building. Also recommends that any changes to the MRA with Europe (for IVD medical devices) not be made until the introduction of the revised European IVD framework. Is opposed to all applications supported by non-MRA Notified Body certificates undergo a mandatory application audit. This would require many Class 2 and 3 products under the IVD regs to require a mandatory application audit which was a key negotiation point of the IVD framework. Also concerned that the proposal will exclude high quality notified bodies that chose not to sign up to the MRA.
44	Ivoclar Vivadent Pty Ltd	No comment.
45	Johnson & Johnson Medical Pty Ltd	Supports and believes that this should be extended beyond the MRA to include Notified Bodies from which CE certifications are accepted instead of TGA conformity assessment certification.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment.

47	Magic Mobility (Red Milawa Pty Ltd)	No comment.
48	MAQUET Australia Pty Ltd	Another option is to only accept CE certificates from MRA notified Bodies as manufacturer evidence.
49	Max Boccardo Associates	Support. Strongly objects to linking this to 2C (ii).
50	Medical Technology Association of Australia (MTAA)	Recommends that: • A two year period for confidence building with alignment of requirements between approval of Notified Bodies outside of Australia, and those within Australia, with TGA as the accreditation authority; and • The use of JAS-ANZ processes or equivalent for accreditation processes and consideration of inclusion of bodies such as those accredited by USFDA and MHLW in Japan.
51	Medtronic Australasia Pty Ltd	TGA continue confidence building for a maximum of two years but also actively assess which Notified Bodies should be on the MRA approval list.
52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	Welcomes a continued MRA system for Class IIb and encourages the concept of qualifying individual notified bodies as capable of mutual recognition through confidence building.
55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Support but suggest that it be undertaken with caution to ensure that companies with CE certificates from Notified Bodies that have not undergone confidence building are not adversely affected.
57	Otto Bock Australia Pty Ltd	No comment.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	The use of this process will not increase unless Class III devices are included and TGA is not the only certifier for Class III devices. Disappointed at the TGA's lack of commitment to the MRA process by not having already initiated the confidence building process. What does the TGA expect from a confidence building exercise or how it should be structured? The objectives and the outcomes of the confidence building process should be published. TGA should consult the medical device industry to determine which Notified Bodies should be considered acceptable to continue with or be part of the MRA then approach the competent authorities that designated them for further advice. As a part of the MRA the Department of Health and Ageing should be part of the regular EU Notified Bodies Operation Group audit program of Notified Bodies. Should model the

		confidence building accreditation processes on what the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) does to accredit certification companies and EU competent authorities does to designate Notifying Bodies.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	No comment.
61	Queensland Health– Chief Health Officer	Support.
62	Queensland Health– Centre for Healthcare Improvement	No comment.
63	Resmed	Support. For low and medium risk devices certificates issued by an EU notified body (93/42/EEC) should be acceptable. Also question if the intent of the proposal should include any third party certifying body assessed by the TGA as capable.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	Support. Believe it will strengthen the utility of the MRA and benefit both European manufacturers and the Australian public.
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Case not adequately justified for further confidence building. TGA should elaborate why it is needed. Believe MRA should be extended to allow assessment of devices which require a TGA conformity assessment ie containing medicinal or animal content to allow simultaneous assessment by a European Notified Body for entry to the Australian and European markets.
68	Stryker Australia	TGA provide a clear objective surrounding confidence building. For TGA to increase the confidence level of a Notified Body an accreditation process should be introduced with appropriate training to improve the Notified Body's understanding.
69	STS Health	No comment.
70	N/A	N/A
71	The Pharmacy Guild of Australia	Support.

72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Propose implementing an accreditation and monitoring program for third party assessors. How will third party bodies be accredited, monitored and what is their role in reviewing and assessing all classes of medical devices.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 2C(ii)

#	Respondent	Response
1	3M Australia Pty Ltd	No impact therefore no comments.
2	Abbott Australasia P/L (Diagnostics Division)	This proposal is encouraged as it provides flexibility for Australian manufacturers and has the potential to reduce regulatory burden. Questions the requirement to base the assessment bodies in Australia. Recommends that TGA put in place a process to designate any suitable authority or body to undertake conformity assessment.
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	No comment.
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position.
5	Amgen Australia	No comment.
6	AMPAC Dental Pty Ltd	No comment.
7	ANZ dental	No comment.
8	AusBiotech Ltd	Supports. Suggests that where an acceptable overseas competent authority has designated a conformity assessment body then this should be acceptable by the TGA as meeting Australian requirements. The TGA could be an accrediting body whilst also being subject to independent assessment if it intends to continue to act as a conformity assessment body.

9	Australian Dental Association Inc (ADA)	Support. Will increase competition and choice for Australian manufacturers seeking the services of an assessment body.
10	Australian Dental Industry Association Inc (ADIA)	Support as it will increase competition amongst assessment bodies that support the Australian dental industry.
11	Australian Health Insurance Association (AHIA)	Support- the TGA should investigate the potential accreditation process being conducted by a third party body either locally (QA focussed) or overseas.
12	Australian Orthopaedic Association Limited	Prefer that clinical assessments were undertaken within Australia.
13	Baxter Healthcare Pty Limited	No comment.
14	BIOTRONIK Australia Pty Ltd	Fully supports.
15	BORG Dental (Bordent Pty Ltd)	No comment.
16	Bosco Medical Australia	No comment.
17	Bourke Dental Supplies	No comment.
18	CareFusion Australia & New Zealand	This is a positive initiative.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	No comment.
21	Consumers Health Forum of Australia (CHF)	Supports.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	No comment.
24	Dentalife Pty Ltd	No comment.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Not directly relevant but support moves by the TGA that increase the choice of Australian medical device manufacturers seeking the services of an assessment body.

27	Department of Innovation, Industry, Science and Research	Fully supported but has concerns that this does not appear to be an urgent area of reform.
28	Device Technologies Australia Pty Ltd	Proposes the TGA develop a system, within two years, by which third party assessment bodies can apply for designation to be given authority to issue Australian Conformity Assessment Certificates.
29	Draeger Medical Australia Pty Ltd	No comment.
30	Dynek Pty Ltd	Proposal 2C(ii) further undermines Proposal 2C(i). If a model can be presented for Australian based assessment bodies why hasn't the TGA already done this with the EU notified bodies over its seven years experience. The recent release of the "TGA risk based approach to audit frequency" will exacerbate the costs associated with TGA audits. TGA's explanations for introducing a more frequent audit regime show little understanding of the costs involved in making substantial changes in manufacture, including: staffing; procedures; equipment or location; and the validation of any change.
31	EBR Regulatory Affairs Consultants	The recognition of third party assessments is taking too long. It is not clear if the TGA has a role in designating CABs via the MRA.
32	Erskine Dental	Welcomes this initiative.
33	Essology Pty Ltd	No comment.
34	Fisher & Paykel Healthcare Limited	No comment.
35	GE Health Care Australia Pty Ltd	No comment.
36	GlaxoSmithKline Australia Pty Ltd	No comment.
37	Gunz Dental Pty Ltd	No comment.
38	Healthlinks.net Pty Ltd	No comment.
39	Henry Schein Halas	Support as it will increase competition amongst assessment bodies that support the Australian dental industry.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment.
41	Integra Neurosciences Pty Ltd	No comment.
42	Invacare Australia Pty Ltd	No comment.
43	IVD Australia	Is supportive in principal but seeks additional detail on the determination of appropriate third party assessment bodies and whether they will be required to have a physical presence in Australia. Questions the need to have the

		assessment body based in Australia which is such a small market and may not get any interest. Also recommend that a separate office to the Office of Device Authorisation be set up to designate if the TGA is to designate.
44	Ivoclar Vivadent Pty Ltd	No comment.
45	Johnson & Johnson Medical Pty Ltd	Supports in principle although questions if there is sufficient volume of work to sustain an Australian third party conformity assessment body. Propose that CABs should not have to have physical or legal presence in Australia.
46	Johnson & Johnson Pacific and Vision Care Australia	No comment.
47	Magic Mobility (Red Milawa Pty Ltd)	No comment.
48	MAQUET Australia Pty Ltd	No comment.
49	Max Boccardo Associates	Support. Suggests TGA no longer undertake CAs but oversight independent third party assessors or alternatively find an independent controlling body for all conformity assessors such as JAS-ANZ.
50	Medical Technology Association of Australia (MTAA)	Recommends that TGA take on the role of the accreditation authority to accredit conformity assessment bodies in Australia. If TGA is to be a conformity assessment body then it must be independently assessed, for example JAS-ANZ.
51	Medtronic Australasia Pty Ltd	Propose TGA retain its role as the Australian Competent Authority and its role as a Conformity Assessment Body. Propose that an independent body be the Designating Authority such as JAS-ANZ.
52	Multigate Medical Products Pty Ltd	No comment.
53	National Serological Reference Laboratory (NRL)	Propose uniform criteria and guidance for bodies that may become Australian third party assessment bodies to avoid bodies with different standards providing different quality of assessment.
54	Nobel Biocare Australia Pty Ltd	Welcomes a continued MRA system for Class IIb and encourages the concept of qualifying individual notified bodies as capable of mutual recognition through confidence building.
55	Novo Nordisk Pharmaceuticals Pty Ltd	No comment.
56	NuVasive Australia & NZ Pty Ltd	Support but suggest that the TGA ensure that this system copies the Competent Authority plus notified body arrangement in the EU that is a company that receives a CA certificate from the TGA-certified Australian based assessment body doesn't have to also submit an application to the TGA.

57	Otto Bock Australia Pty Ltd	No comment.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Supports. Should model the certification/recognition process on the one used in Europe for their respective legislation for consistency and harmonisation. The objectives and outcomes of the ongoing certification/recognition process should be publicly available to demonstrate the TGA is ensuring compliance. Support a single competent authority, TGA, to designate Australian third party assessors but not the TGA to offer CA services.
59	Pfizer Australia Pty Ltd	No comment.
60	Queensland Health- Clinical and Statewide Services Division	No comment.
61	Queensland Health– Chief Health Officer	Support. Please refer to Division of Chief Health Officer previous proposal and consider future involvement during the system development phase.
62	Queensland Health– Centre for Healthcare Improvement	No comment.
63	Resmed	Support. Has the potential to provide flexibility for Australian manufacturers. Should ensure Australian third party assessment bodies are not disadvantaged with respect to either EU Notified Bodies or the TGA.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	No comment.
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Supports. Further consultation is required.
68	Stryker Australia	Supports and recommends that the TGA take on the accrediting role but no longer conformity assessment certification itself. Also allow bodies to be situated in both Australia and overseas.
69	STS Health	No comment.
70	N/A	N/A
71	The Pharmacy Guild of Australia	Support. Important that arrangements continue to meet high standards. Supports mandated TGA certification of devices classified as higher risk. Notes that it does not preclude the TGA from capitalising on rigorous overseas assessments. Also supports open and transparent discretion by the TGA to implement similar requirements for

		lower risk devices.
72	TrioDent Ltd	No comment.
73	WelchAllyn	No comment.
74	Whiteley Corporation Pty Ltd	No comment.
75	William Green Pty Ltd	No comment.
76	Zimmer Pty Ltd	Propose TGA take on the role of designating body and make final regulatory decision but concerned at the conflict of interest if TGA is also a designating body.
77	Zoono Solutions Pty Ltd	No comment.

Proposal 3

Proposal 3(i)

#	Respondent	Response
1	3M Australia Pty Ltd	Do not support because: • Itemising will not enhance the consumer or patient's ability to identify registered products as often it is the health professional using the product; • Dental and orthodontic products maintenance of products by item number is a huge undertaking – several hundred items per same kind of device- and benefit is questionable; • Suggest listing of brand names as an alternative, similar to prescription and OTC; • Transition period is too short; and • Will result in a significant ongoing cost as the sponsor would be paying for each new item added.
2	Abbott Australasia P/L (Diagnostics Division)	Recognises the limitations of the current regulatory system. Suggests that inclusion of model numbers and variants for IVD devices be optional. For low and medium risk devices not requiring assessment recommends that sponsors be able to update/vary their entries to add new models as an auto update to the ARTG through eBS with no pre market oversight or fee increase. Higher risk devices to continue to require an assessment including new products. Do not support any proposal for further IVD devices to undergo an assessment to allow an addition of a new/product or model to an existing inclusion on the ARTG. Are willing to supply the TGA with the Document of Conformity Assessment (DoC) but do not support its

		inclusion on the TGA website as a public document as the DoC: • Could contain confidential information; • Would mean little to the general public; and • May take on a variety of forms from manufacturers, making it difficult to interpret the information. Suggest that the only information of value to stakeholders would be the names of the medical devices which could be provided as a simple table under the ARTG inclusion.
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	Tentatively accept provided that the assessment requirement is removed for devices that are Class IIb and above. Are not aware of any failures in the system to warrant their increased assessment. Tentatively supports creating a list of all medical devices that are included under an ARTG entry as long as there is no fee and the TGA eBS system can cope. Will address TGA's need for increased post market monitoring.
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position.
5	Amgen Australia	Should apply to Class III and above. The regulatory burden and ARTG burden to list different models doesn't match the benefit for low risk items.
6	AMPAC Dental Pty Ltd	Would place an additional burden and result in additional costs. Would like TGA to define the specifics of a model and when sponsors must notify the TGA of changes.
7	ANZ dental	Will result in a large one off cost and increased ongoing costs. Transition time is too short. Suggests listing the device name on the ARTG to avoid increased compliance costs.
8	AusBiotech Ltd	Supports this proposal in principle. Notes that industry requires clarity on requirements, definition of models, and individual devices. Concerned that this could cause huge increases in item listings and resultant increases in administrative burdens and increased regulatory costs. The requirement for an application for variation for each subsequent addition on new devices/models could result in extensive lists of products that may make it harder for healthcare professionals and the public to access relevant information.
9	Australian Dental Association Inc (ADA)	Concurs with the ADIA. Preferred alternative to list the product name on the ARTG entry for a medical device. Timeframe is too tight. Propose two years.
10	Australian Dental Industry Association Inc (ADIA)	Not supported in its current form as it will add significantly to the regulatory compliance costs and hence consumers. Ambiguity in how the TGA will require sponsors to itemise the devices, by model number, model or trade name. Advice to the ADIA from the dental industry arising from this proposal would require fifty new model applications each week impacting on processing times. Recommends a 3 year implementation. Proposal

		is inconsistent with the *OECD Guiding Principles for Regulatory Quality and Performance*. It is expected that the dental industry will be required to provide nearly 30000 new data items over the twelve month period with an estimated increased compliance cost of 1-1.5% to industry over the twelve months. With 4000 entries requiring amendment annually and an ongoing regulatory compliance cost to industry of 0.75%. Recommends trade name be used.- Define new model. Update eBS portal to allow sponsors to update on a fee free basis. Update ARTG website to allow search by trade name and 24 months be given for implementation.
11	Australian Health Insurance Association (AHIA)	Support- The National Product Catalogue should be used to capture device details across industry.
12	Australian Orthapaedic Associaiton Limited	Agrees with the approach as they are outlined in the proposal.
13	Baxter Healthcare Pty Limited	Recommends that this part be adopted. Sponsors to provide the TGA with a list of registered devices identified by model number, product catalogue number or trade name under each ARTG entry.
14	BIOTRONIK Australia Pty Ltd	Understands and supports the proposal, however rejects any proposal to place the ARTG number on the label on the product as it would require country specific labelling which is not feasible.
15	BORG Dental (Bordent Pty Ltd)	Do not support. Increased regulatory burden due to the increased size of applications and required IT and maintenance. Increase time to market and discourage companies and suppliers from introducing updated devices into Australia.
16	Bosco Medical Australia	Suggest that the transition period be 24 months and that no fees be charged for the variance.
17	Bourke Dental Supplies	Do not support. Increased applications required and increased burden on IT requirements.
18	CareFusion Australia & New Zealand	This proposal is confusing as it only applies to Class IIb or above. Sponsors will simply include one or two models at the first application, then add all the rest of the models later to avoid unnecessary scrutiny by the TGA.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	This proposal goes further than the Recommendation 8 of the HTA review as it includes all devices not just higher risk devices. Inclusion and variation costs could deny access to new models. The list will allow ready access by organisations to their competitors' full listing of approved devices. Propose to allow sponsors to update within a defined period of time a list of models in a sponsor/TGA restricted area of eBS ARTG. Define a list of variants that assessment would not be required and make fees nominal for a variation if any especially if sponsors upload the material themselves.

21	Consumers Health Forum of Australia (CHF)	Support the proposal to itemise the devices and various models to allow better tracking for safety. Consumers wish to see greater harmonisation between Australia and international processes. Suggests that TGA undergoes a program of information sharing with bodies recognised under the MRA and remains up to date with current international trends.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	This will result in a substantial one off cost and ongoing costs. Prefers to list the product names of devices in the ARTG entry rather than the model name allowing more model updates that do not considerably alter the devices function to be updated at minimal cost. Also support a 2 year time frame.
24	Dentalife Pty Ltd	Strongly support. Will increase transparency of the TGA regulatory approval for medical devices and enhance identification to legally supplied approved medical devices. Will also give healthcare providers and consumers' confidence in the use of the product.
25	Dentaurum Australia Pty Limited	Will result in a very large initial one off cost and significant ongoing costs.
26	Dentsply (Australia) Pty Ltd	Will lead to increased regulatory burden for lower risk devices where there are large numbers of devices. No detail provided in the paper of a clear demand for this information from either oral healthcare practitioners or consumers. Do generally agree that the ARTG could be improved by linking an individual entry with models of a particular device. This needs to be carefully balanced against introducing an excessive regulatory regime which delays new product approvals or prohibits new products. The TGA must clearly define which changes would be considered significant. An alternative would be to list the product name on the ARTG with the allowance made for a number of names to be included under a single ARTG entry where all are the same kind of device. Variations could be automatically added and subject to audit as Class I is now and based on level of risk. A two year timeframe is more realistic.
27	Department of Innovation, Industry, Science and Research	Not enough information to fully assess the proposal. Broad industry adverse reaction to the implications of an Australian specific requirement on individual medical devices.
28	Device Technologies Australia Pty Ltd	Cannot support as there is insufficient detail to determine the impact and feasibility. Propose: Class I non-sterile, non measuring devices are excluded; identification is through a fee free notification system for all classes; removal or amendment of model or trade names should not incur a fee or undergo review; information is automatically accepted: post-market audits used to review content; identification by model or trade name is determined by the sponsor; flexibility is employed to accommodate the vast range of product types and naming conventions; and the TGA develop with industry a resourcing plan to assess the number of expected applications. Also proposes a significant fee reduction and proposes TGA implement faster processing times to

		vary inclusions.
29	Draeger Medical Australia Pty Ltd	In principle support. Should not require a complete new application when new models become available. Any cost should be covered by the annual licence fee. Propose that the initial entry be amended/varied and a manufacturer declaration of conformity for the new model be attached as evidence of the required conformity assessment. Recommend a 3 month window before the 12 month timeframe is introduced.
30	Dynek Pty Ltd	Such a list would exceed 9000 models and would do little to achieve the TGA's aims. If the TGA charges the cost would be prohibitive. Require clarification on the extent of this proposal.
31	EBR Regulatory Affairs Consultants	Why do we need to do this? How does having this information add to the safety or quality of the device? If accepted there should be no fees associated with it. 12 month transition is too short.
32	Erskine Dental	Do not support in its current form. Will result in a large one off cost and increased ongoing costs.
33	Essology Pty Ltd	Concerned at the practical implications of the consumer/patient benefit. Also questions how reusable devices will be treated?
34	Fisher & Paykel Healthcare Limited	Agree with the general principle which is consistent with other regulators. Would like further clarification of the costs involved. The addition of one model number to an already approved ARTG number should not attract the same application fee as a new submission, particularly if the device is Class IIb or below. Also would like a definition of the assessment that an application to add a model number to Class IIb ARTG entry would undergo. Define model number and trade name. Preference would be to have model number as the minimum requirement but with an option of also having trade name listed. Ensure that a process is included for removing products from the ARTG entry.
35	GE Health Care Australia Pty Ltd	Would require a 2 year transition period. Require further clarification of the fee to be charged by the TGA to vary the inclusion after the transition period.
36	GlaxoSmithKline Australia Pty Ltd	Fully supports. The proposed transition period of 12 months at no cost seems reasonable. However cost should be minimal to lodge a variation application to register a new model or trade name after the transition period. It should reflect the amount of data submitted by sponsors and the time taken for TGA to assess it.
37	Gunz Dental Pty Ltd	Supports this position. Other than complete identification of every device line item which substantially alters the existing regulatory arrangements for the business. An impossible task to identify every line item of device that currently sits under an ARTG entry. For 35000 items it will require substantial IT burden and cost to maintain. To be subjected to the requirement for variation and not knowing how much this will cost and if TGA audit is also required will increase time to market. This will actively discourage companies and suppliers from introducing updated devices. Large one off cost and significant ongoing costs. Best practice will be reduced

		along with end users choice.
38	Healthlinks.net Pty Ltd	No comment.
39	Henry Schein Halas	Not supported in its current form as it will add significantly to the regulatory compliance costs and hence cost to consumers. Ambiguity in how the TGA will require sponsors to itemise the devices, by model number, model or trade name. Advice to the ADIA from the dental industry arising from this proposal would require fifty new model applications each week impacting on processing times. Recommends a 3 year implementation. Proposal is inconsistent with the *OECD Guiding Principles for Regulatory Quality and Performance*. It is expected that the dental industry will be required to provide nearly 30000 new data items over the twelve month period with an estimated increased compliance cost of 1-1.5% to industry over the twelve months. With 4000 entries requiring amendment annually and an ongoing regulatory compliance cost to industry of 0.75%. Recommends trade name be used.- Define new model. Update eBS portal to allow sponsors to update on a fee free basis. Update ARTG website to allow search by trade name and 24 months be given for implementation. Suggest using the declaration of conformity and keep entries at the GMDN level. Could link the declaration to the public domain.
40	Independent Rehabilitation Suppliers Association (IRSA)	Will result in significantly increased costs, reduced competition, less choice for consumers with disabilities and potentially drive individuals towards unregulated importation. Not consistent with global harmonisation, does not see any safety or quality benefits. It may be impossible to undertake for many sponsors as they source from multiple manufacturers.
41	Integra Neurosciences Pty Ltd	Require a longer implementation period. Estimating stock depletion is not easy with devices as many do not have an expiration date.
42	Invacare Australia Pty Ltd	This will not enhance the identification of approved devices. If implemented no fees should be charged for future variations to include additional products. Would require a 2 year transition period.
43	IVD Australia	Questions the cost benefit and has concerns at the cost to sponsors. Recommends that: IVD medical devices be included at the family level for Class 1 and 2 IVDs; notification of changes to product details as proposed be available through the eBS at no charge and only required annually; variation of inclusion only be used for substantial changes; and the transition period be 3 years.
44	Ivoclar Vivadent Pty Ltd	Will cost a lot of time and energy. IT costs will be substantial at the outset and ongoing.
45	Johnson & Johnson Medical Pty Ltd	Support. Provided the system can be electronically updated by the manufacturer at no cost with a notification system.
46	Johnson & Johnson Pacific and	Supports. Need clarity of the definition of an individual device, clarity on the process of how products will be

	Vision Care Australia	included on the ARTG. Suggest the system as is used for other therapeutic goods such as tampons? Proposes a fee free notification system or a minimum fee to cover administration only.
47	Magic Mobility (Red Milawa Pty Ltd)	Propose to itemise their wheelchairs at the platform level otherwise they would be put out of business. Each wheelchair they manufacture has a serial number already on it. Costs would be prohibitive. No fees should be charged. 12 months is too short for the transition period. Commented that there was one token consultation in Melbourne and they were not invited.
48	MAQUET Australia Pty Ltd	An alternative could be greater application of the penalties already available to the TGA when non-compliance is identified. Should this go ahead suggest that there is no fee to vary inclusions?
49	Max Boccardo Associates	Not supported. Require further validation of concerns.
50	Medical Technology Association of Australia (MTAA)	Recommends that: • TGA provide for identification of medical devices on the ARTG through a fee free notification system, supplemented by post market audit; and • The transition period be extended for two years.
51	Medtronic Australasia Pty Ltd	Supports and proposes a fee free notification system through eBS.
52	Multigate Medical Products Pty Ltd	Will have an impact on many of the different procedure packs that are produced for specific hospitals or surgeons. Will impose an inappropriate burden on both the company and the TGA for the level of safety and performance.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	Would like TGA to define the specifics of a model and what constitutes a specific change. Propose a requirement for a model name (but not a model number) with TGA modification needed only when a significant change takes place. Will lead to a large one off cost and significant ongoing costs. Recommend a 2-3 year transition time.
55	Novo Nordisk Pharmaceuticals Pty Ltd	Support but should not require TGA approval. Would increase level of regulatory burden to be greater than the risk.
56	NuVasive Australia & NZ Pty Ltd	Does not support. Result in significant additional burdens and it is unclear how the process will improve TGA approval confirmation. Concerned that additional assessment will be needed each time a new product is added, with additional fees and longer approval times. This could cause delays in the availability of new models.

57	Otto Bock Australia Pty Ltd	Proposal looks like revenue raising. Is this the first step in getting an ARTG for all devices? How does having this additional information add to the safety and quality of a device? Changing the definition will not enhance the identification of approved devices. If accepted then should be fee free. 12 months is too short. Suggest TGA use other methods than further regulating the industry to deter people from manipulating the process.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	How does having this additional information add to the safety and quality of a device? Only allows notification without any prior validation before appearing on the ARTG. The maintenance cost will increase from between $20 000 to $180 000. Should be no fee associated. Does not support the proposal to submit variations for additional products after the transition. New updated devices could amount to 200-500 variations per week leading to unnecessary delays due to the increased processing times. Recommend to use a fee free notification process using the online eBusiness system. Use the ARTG to identify all additions and undertake reviews according to the classification and the GMDN code similar to the Class I process.
59	Pfizer Australia Pty Ltd	Requires further information regarding on what basis applications will be assessed and approved and whether significant technical data would be needed. Also seeks clarification whether lower class devices would be included. Proposal would have significant impact on the cost of medical devices, especially lower risk devices. Suggest the use of a fee free notification system for lower risk devices. The number of new listings on the ARTG may slow the website down. Itemisation of devices is already detailed on the Australian Declarations of Conformity and this could be supplied to the TGA via notification without a new application being required. Costs will be incurred to maintain numerous entries on the ARTG when there was previously only one. Would like clarification on the charges associated with multiple variations.
60	Queensland Health- Clinical and Statewide Services Division	Welcome improvements to the way in which medical devices will be included in the ARTG.
61	Queensland Health– Chief Health Officer	Support as experience has shown that some ARTG certificates have limited product information.
62	Queensland Health– Centre for Healthcare Improvement	Fully support. The model field should be searchable to allow improved search capability of the ARTG.
63	Resmed	Support for low and medium risk devices not requiring assessment. Sponsors should be able to update or vary their entries to add new models as an automatic update of the ARTG. There should be no pre-market oversight or fees associated. Higher risk devices requiring an application audit should continue to require an assessment. Opposes any requirement for Class IIb (other than Class IIb implantable) devices to undergo an assessment to allow addition of a new model. Will add significantly to the regulatory overhead and is not justified by the level of risk.

64	Royal Australasian College of Physicians (RACP)	Supports the use of post marketing safety and surveillance for medical devices.
65	RTI Biologics Inc	Recommend that the costs associated with "assessment of subsequent variations" be proportioned according to the level of assessment required.
66	Seating Dynamics Australia Pty Ltd	Changing the definition will not enhance the identification of approved devices. How does having the additional information add to the safety or quality of the device? TGA should prosecute those manipulating the system and publish outcomes. If accepted then no fees should be charged. 12 month transition is too short considering the amount of information required.
67	Smith & Nephew Pty Ltd	Supports provided it is a fee free notification process. Does not adequately specify the level at which individual products are to be entered onto the ARTG. Specificity of product detail to be entered on the ARTG should not exceed that which is reasonably required by a user to identify a product.
68	Stryker Australia	Increases ongoing administrative costs if additional assessment is added. Recommend implementing a fee free notification process managed via eBS.
69	STS Health	Overall support, however would like a description of what constitutes new model and caution on setting the bar too high and causing delays and frustration. Concerned at the increase in compliance costs will result in large one off charges and significant ongoing costs.
70	N/A	N/A
71	The Pharmacy Guild of Australia	Supports to improve the useability of the ARTG. Would like improved search functions for the ARTG. Would also like to see distinct categories with the ARTG Public summary standardised. Currently this is inconsistent. "Active ingredient" is a search function for devices which is not applicable. Believes maintaining entries should be a shared responsibility of industry and the TGA, to monitor.
72	TrioDent Ltd	Need definition of what a model is and what changes constitute a new model. Results in a very large one off cost and significant ongoing costs.
73	WelchAllyn	Recommend that: Class I products are still automatically included on the ARTG; any additional products included in that registration should be also automatically included within a 24 hour turn around using a variation process; and Class I products continue under the current Post-market vigilance and monitoring program. For Class I measure, Class IIa, Class IIb: continue using the method for application of manufacturers evidence with a 2 week turnaround with the relevant certification and documentation; require the relevant product codes for all device applications with no change in application fee; and have a variation submission process for adding additional part numbers to products that have been issued the relevant conformity assessment documentation at a

		minimal fee.
74	Whiteley Corporation Pty Ltd	Currently proposal is unclear of the process the TGA will use to include kinds of device. Sponsor should submit a notice of intention to market the product onto the eBS website without a full assessment by the TGA. This will allow TGA to know all of the products under an ARTG number but also reduce any regulatory costs or impacts on time to market.
75	William Green Pty Ltd	Need definition of what a model is and what changes constitute a new model. Recommend TGA consult with industry on what constitutes a significant change. Transition time should be 3 years. Result in substantial one off cost and significant ongoing costs.
76	Zimmer Pty Ltd	Support. Propose that TGA accept the identification for existing Class III devices that have Design Examination Certificates issued by accepted Notified Bodies. For new Class III applications the sponsor should make the identification in the application. For Class IIb the sponsor should make the identification for both new and existing applications.
77	Zoono Solutions Pty Ltd	Propose to either use GTIN numbers or align the eBS with the National Product Catalogue.

Proposal 3(ii)

#	Respondent	Response
1	3M Australia Pty Ltd	Overseas manufacturers would need to require special production lines for Australian market resulting in additional costs. The transition period is too short. Likelihood that some small volume products would no longer be supplied to the Australian market.
2	Abbott Australasia P/L (Diagnostics Division)	Does not support. Benefit does not outweigh the regulatory impost. Other major device regulated markets- EU, USA and Canada do not require this. Not the best way for a consumer or health practitioner to use the specific ARTG number to obtain the latest information as this usually resides with the manufacturer or sponsor. Questions whether this would enhance the ability to identify TGA approved devices as unscrupulous suppliers could mock ARTG numbers leading to less checking by end users. Suggests that this will increase costs to label as it will require new local labelling requirements for importers. Recommends that the ARTG allow searching by manufacturer coupled with implementation of proposal 3(i) would suffice.

3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	Do not support. Believe proposal 3(i) is sufficient and this will be an additional regulatory burden without any foreseeable benefits. Members have indicated that this will require a change to every label template and create Australian only labelling for international members.
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position.
5	Amgen Australia	Supports but clarification is sought on where the ARTG will appear.
6	AMPAC Dental Pty Ltd	A large proportion of products are manufactured overseas. This would result in time delays and substantial costs.
7	ANZ dental	Will result in a large one off cost and increased ongoing costs. Transition time is too short. Suggests listing the device name on the ARTG to avoid increased compliance costs.
8	AusBiotech Ltd	Does not support. Concern at the: available space on devices; additional resources required for the management of existing inventories which may have to be relabelled; and timeline for implementation. It is expected to be costly and labour intensive and a duplication of effort with the eBS system. Suggest an improved eBS interface and search function and alternative technologies such as RFID tags.
9	Australian Dental Association Inc (ADA)	TGA has not demonstrated a clear demand from either healthcare practitioners or consumers. Clearly define the intent of the label. Proposal is problematic for overseas manufactured devices requiring special runs increasing costs. Could be achieved by listing the product name under the ARTG number.
10	Australian Dental Industry Association Inc (ADIA)	Not supported in its current form as it will add significantly to the regulatory compliance costs. TGA's proposal is unclear and needs further drafting for further consultation. TGA is yet to establish a case for the reform and the need for increased regulation. Suggest that the number be required on the information rather than the device. Proposal implemented 24 months from legislative change. 3(i) achieves the aim of this proposal.
11	Australian Health Insurance Association (AHIA)	Support- The National Product Catalogue should be used to capture device details across industry.
12	Australian Orthapaedic Associaiton Limited	Agrees with the approach as outlined in the proposal.
13	Baxter Healthcare Pty Limited	Concerned that implementation will be logistically untenable. Suggest publishing the ARTG number on the information provided. Baxter Healthcare Pty Limited estimates an overlabelling operation would result in additional costs of $250 to $500 per unit.

14	BIOTRONIK Australia Pty Ltd	No comment.
15	BORG Dental (Bordent Pty Ltd)	Do not support. Believe that end user is the dental professional and they can track products using the ARTG entry on invoices and dispatch notes.
16	Bosco Medical Australia	Would have a detrimental impact on supply chain, in particular disruptions to the manufacturing process to change print formats for Australian products increasing costs and delivery times. Some suppliers have suggested that this would take a long time to implement if at all. Possibly leading to some products no longer being supplied to the Australian market. Suggest placing all the material on the company's website.
17	Bourke Dental Supplies	Do not support. Increased cost burden and increased process time for dispatch of product. Tracking can already be undertaken by using the ARTG entry on invoices and despatch notes.
18	CareFusion Australia & New Zealand	This is not achievable as the majority of devices on the Australian market are imported. Requiring overseas manufacturers to create dedicated labelling, IFU or packaging for the small Australian market is unrealistic and may cause withdrawal of products. It seems the TGA is trying to regulate devices similarly to medicines. This is impractical as devices regularly have many changes unlike medicines and each medicine has a unique Aust R number whereas there are multiple entries for devices. Attempting this would make the process too onerous and unworkable for devices.
19	Carl Zeiss Vision	Do not support. Suggests that this will increase costs to label as it will require new local labelling requirements for global supply. Increased cost burden and serves no real value to customers. Propose that Class 1, especially non-sterile, non-measuring, be exempt. Alternatively propose that sponsors include a list of all ARTG numbers which they sponsor or manufacture supplied on the shipping list or on the invoice.
20	ConMed Corporation	Medical device packaging is directed at the health professional not consumer like medicines. Significant cost implication to provide this information.
21	Consumers Health Forum of Australia (CHF)	Support the proposal to place the ARTG number on devices and various models to allow better tracking for safety. Consumers have also called for greater clarity around which agency or group is responsible for reviewing obsolescent devices/technologies and defined criteria to determine obsolescence.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	Would like further clarification wether it is an adding the ARTG number to the packaging or to the device. Do not support if it is the device as the costs imported products will rise.
24	Dentalife Pty Ltd	Strongly support. Will increase transparency of the TGA regulatory approval for medical devices and enhance

		identification to legally supplied approved medical devices. Will also give healthcare providers and consumers confidence in the use of the product.
25	Dentaurum Australia Pty Limited	Will result in a very large initial one off cost and significant ongoing costs.
26	Dentsply (Australia) Pty Ltd	Support 3 (i) over 3 (ii) as if 3 (i) goes forward 3 (ii) would unnecessary. This would require overseas manufacturers to create dedicated labelling and new artwork leading to increased costs and delays in marketing products in Australia or even withdrawal.
27	Department of Innovation, Industry, Science and Research	Not enough information to fully assess the proposal. Broad industry adverse reaction to the implications of an Australian specific requirement on individual medical devices.
28	Device Technologies Australia Pty Ltd	Does not agree that this is the best approach. Proposes that regulation 10.2 and EP 13.2 be reviewed to allow more appropriate labelling of current sponsor details.
29	Draeger Medical Australia Pty Ltd	Suggest that this will be overly onerous to undertake due to increased labour time and costs of labelling. Also the risk that devices could be incorrectly labelled. Over the last three years all suppliers of medical devices to Australian public healthcare institutions have provided ARTG numbers to the National Product Catalogue. If 3(i) is implemented the device will already be easily identified.
30	Dynek Pty Ltd	Consideration needs to be given to the available space on device labels, and stipulations on minimum font size of ARTG numbers Manufacturers are likely to hold considerable stock of existing packaging/IFUs and consideration must be given to allow companies to work through these stocks.
31	EBR Regulatory Affairs Consultants	Enormously expensive with very little to no gain for safety or quality. Based on a medium sized supplier of a US made product ($50-80 million in revenue) moving 60000 cartons a month approximately 5 to 8 cents if it can be automated or 25 to 30 cents if not. The cost would be between $36, 000 to $57,000 if automated or $180,000 to $216,000 if done manually. This does not take into account any new equipment or labour costs or controls that would need to be put in place to check. The majority of sponsors in Australia distribute for more than one manufacturer further compounding the problem. Also some sponsors direct ship products to their customers making it difficult to control or check the numbering. A RIS needs to be undertaken on this proposal by itself and costs should be able to be provided to DOFD directly. Questions what to do about reusable product, these should be excluded. 12 month transition is too short.
32	ErskineDental	Difficult to support. Will result in a large one off cost and increased ongoing costs.

33	Essology Pty Ltd	Process would be error prone and would result in increased costs.
34	Fisher & Paykel Healthcare Limited	Do not see benefit of implementing this as well as 3 (i). Reject. Places a massive regulatory burden on manufacturers, distributors and sponsors. Increased costs to create Australian only product lines. What is the risk the TGA is trying to address with this proposal? Its introduction will not stop disreputable suppliers.
35	GE Health Care Australia Pty Ltd	Will require significant effort and resources to undertake this. Recommends a label with a website reference to ARTG listings to reduce the risk of an incorrectly labelled device. Clarification if the transition period applies to new products only or if it is retrospective.
36	GlaxoSmithKline Australia Pty Ltd	Fully supports. However believe it should be limited to the outer packaging of the device to reduce artwork costs and avoid the impracticality of adding the number to some devices. Suggest increasing the implementation timeframe from 12 to 24 months due to: the number of countries that may be involved; the lead times for new or updated packaging; and to allow write off costs of existing packaging especially for low volume products.
37	Gunz Dental Pty Ltd	Already has a significant track and trace system in place. Requires increased IT equipment and increased costs. Large one off cost and significant ongoing costs. Increased costs to consumers. Could use the invoice and despatch notes.
38	Healthlinks.net Pty Ltd	No comment
39	Henry Schein Halas	Not supported in its current form as it will add significantly to the regulatory compliance costs. TGA's proposal is unclear and needs further drafting for further consultation. TGA is yet to establish a case for the reform and the need for increased regulation. Suggest that the number be required on the information rather than the device. Suggest proposal is implemented 24 months from legislative change. 3 (i) achieves the aim of this proposal.
40	Independent Rehabilitation Suppliers Association (IRSA)	Reusable devices should be excluded. Encourage sponsors to have the ARTG number mentioned for each product on their website. Support prosecution of sponsors who do not comply. Information should be made public of any sponsor found to not comply.
41	Integra Neurosciences Pty Ltd	Require a longer implementation period. Estimating stock depletion is not easy with devices as many do not have an expiration date.
42	Invacare Australia Pty Ltd	What is the real benefit to the consumer or healthcare sector? Not in line with international harmonisation. Dangers with parallel importing leading to not all devices being recalled. Lead to increase in costs leading to consumers sourcing on line products. Enormous cost and complexity with little or no gain in safety and quality. The majority of sponsors in Australia distribute for more than one manufacturer further compounding the problem. Also some sponsors direct ship products to their customers making it difficult to control or check the numbering. May lead to withdrawal of product. Also questions how will reusable product be treated? Suggest

		enhancing the useability of the ARTG, encourage sponsors to have the ARTG number mentioned for each product on their website. Reusable devices should be excluded. Utilise the IRIS report form to track devices. Support prosecution of sponsors who do not comply.
43	IVD Australia	Strongly opposes. However recommends that the: ARTG be modified to enable publically accessible searching by Manufacturer for ease of identification; TGA undertake a Cost Impact Assessment; and that 3 (ii) not proceed if 3 (i) proceeds.
44	Ivoclar Vivadent Pty Ltd	Will increase the cost substantially and increase the dispatch time to the client.
45	Johnson & Johnson Medical Pty Ltd	Does not support. The administrative burden of supplying the ARTG number with the device will introduce additional risk associated with over labelling and will also be costly and unnecessary duplication of information available on the public ARTG. 3(i) achieves the aim of this proposal.
46	Johnson & Johnson Pacific and Vision Care Australia	Do not support. 3(i) achieves the aim of this proposal. This would require overseas manufacturers to create dedicated labelling and new artwork leading to increased costs and delays in marketing products in Australia or even withdrawal. Confusion could be created with different products having the same ARTG and the same products made at different sites that have different ARTG numbers.
47	Magic Mobility (Red Milawa Pty Ltd)	Huge cost and complexity. Consumers would be forced to seek cheaper unregulated products. Questions about resold products. Transition period is too short. Custom devices such as wheelchairs should be excluded. Publicise prosecutions of manufacturers and sponsors.
48	MAQUET Australia Pty Ltd	Suggests that this will increase costs to label as it will require new local labelling requirements for importers. Suggest that the number be required on the information or packaging rather than the device.
49	Max Boccardo Associates	Support. Would provide a level playing field for Australian manufacturers to EU manufacturers supplying products to the Australian market.
50	Medical Technology Association of Australia (MTAA)	Recommends: • Using the enhanced disclosure under Proposal 3(i) coupled with an advanced search capability of the ARTG; • That TGA consider the implementation of a global UDI as a tool to assist with device identification and not replicate what is already in development in other GHTF members; and • Consideration of the use of e-labelling as an option for sponsors of medical devices supplied in Australia.
51	Medtronic Australasia Pty Ltd	Unnecessary as it does not add to safety or efficacy of medical devices beyond proposal 3 (i).

52	Multigate Medical Products Pty Ltd	Propose the use of GTIN through the NPC database. The 12 month transition is too short especially for backtracking products that may have a shelf life of 5 years.
53	National Serological Reference Laboratory (NRL)	No comment.
54	Nobel Biocare Australia Pty Ltd	Unclear if the label is to be provided on the label, instruction for use or packaging. Suggest flexibility as there may not be enough space on the item (small product) and /or deviates from international labelling requirements leading to special production runs just for Australian products increasing costs. Will lead to a large one off cost and significant ongoing costs. Recommend a 2-3 year transition time.
55	Novo Nordisk Pharmaceuticals Pty Ltd	Support but it would be overly bureaucratic to make it mandatory that the inclusion number specifically located on the main panel of the primary packaging as for medicines should this be proposed.
56	NuVasive Australia & NZ Pty Ltd	Does not support. It has significant cost implications. Will need to have multiple Australian Sponsor labels due to different models with different ARTG numbers supplied by the same sponsor.
57	Otto Bock Australia Pty Ltd	What is the real benefit to the consumer or healthcare sector? This is not in line with international harmonisation. One individual product may have multiple parts and the consumer may only see one part so not realising the other part has been recalled. Parallel importing will further confuse the issue as the same product may have different ARTG numbers. Increased costs will lead to consumers sourcing overseas products online. It has significant cost implications. The majority of sponsors in Australia distribute for more than one manufacturer further compounding the problem. Would need separate Australia only runs making the Australian product more expensive. If you place the information on the invoice or shipping documentation the ARTG number will be lost at the distributor when they break down the shipment. Estimate they distribute 2000 items per week and based on cost estimates of 80 cents and $2.20 it would cost between $80 000 and $220 000 per annum not including the purchase of any equipment. Extra costs would be needed to put controls in place. In many case it would require sponsors opening, labelling and repackaging items. It may prevent Australian exporters from supplying other markets as in some jurisdictions it is illegal to place a number on a product that may imply approval. What happens with reusable product? Transition period of 12 months is not enough. Lead to withdrawal of some products. Suggest enhancing the search capability of the ARTG and use existing powers under the Act to prosecute sponsors who are misusing the registration process. Encourage sponsors to have the ARTG number as part of their website. Reusable items should be excluded.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	Estimates a cost of $250 - $500 per product would be incurred to provide artwork. Costs prohibitive. Estimates that there are 1.5 million medical devices on the ARTG that would be affected and approximately 95% are manufactured overseas leading to a cost range for industry from $250 to $750 million. Would lead to many sponsors stripping down product to label each sales unit and repackaging the items back up again further

		increasing costs and time to market and this would also need to include the costs for quality controls. Some sponsors distribute their own product and use several distributors increasing costs further to ensure labelling is consistent. Reusable items would also pose significant practical problems. Proposal 3 (i) achieves the aim of this proposal with the addition of improving the search facilities of the ARTG.
59	Pfizer Australia Pty Ltd	Require further information as to the requirement on devices not currently requiring an instruction for use as requiring it on these products would be a regulatory burden.
60	Queensland Health- Clinical and Statewide Services Division	Welcome enhancement of identification methodologies for approved devices. This would enable improved availability to search the ARTG.
61	Queensland Health– Chief Health Officer	Support with a preference to upgrade the eBS ARTG.
62	Queensland Health– Centre for Healthcare Improvement	Fully support.
63	Resmed	Does not support. Benefit does not outweigh the costs. If 3(i) goes forward this should achieve the goal. Sources of increased costs include: • Global labelling would need to change- different runs for Australian and other country products; • Limited labelling footprints on devices causing regionalised device differences to accommodate the new requirement; and • Delay the release onto the Australian market to gain approval for the new numbering.
64	Royal Australasian College of Physicians (RACP)	Supports the use of post marketing safety and surveillance for medical devices.
65	RTI Biologics Inc	No comment.
66	Seating Dynamics Australia Pty Ltd	What is the real benefit to the consumer? What is the rationale for safety or quality benefits from this proposal? Medical devices should not be compared to medicines. Australian Standards also have labelling requirements. Will increase confusion and frustration to suppliers, manufacturers and consumers. It will be costly for the sponsor. Suppliers could still use made up or other sponsors ARTG numbers to avoid registration. Label does not protect the end user, clinicians or the sponsor/manufacturer who register with the TGA. Additional regulatory costs will drive consumers to purchase products through the internet that have not been assessed by the TGA. Products with multiple parts may confuse consumers as to which is the ARTG number for recalls. Parallel importing also allows multiple ARTG numbers for the same product again making recalls difficult. Causes overseas manufacturers to create Australian only lines. The ARTG number will be lost at the distributor when

		they breakdown the shipment. Estimate cost of adherence will be from $70-$90 000/ year, not including purchase of new equipment or controls. Would require sponsors to open, apply labels and repackage the products leading to increased costs. Direct shipping would also require the overseas manufacturer to add the label further increasing the costs. Australian manufacturers may be disadvantaged as it is illegal in some jurisdictions to place a number on a product that may imply approval. What happens with reusable product? Transition period is too short. May mean fewer products available on the ARTG. Suggest that increase the search capability of the ARTG, increase prosecution rates under existing legislation, publish/provide feedback of these outcomes, and encourage sponsors to have the ARTG number as part of their website.
67	Smith & Nephew Pty Ltd	Rejects. Compliance costs would be high. Generate enormous workload and cost for little gain. S&N operates in 40 countries and sells in > 80 countries and this is not required anywhere else. This may lead to loss of product choice. Puts Australia at odds with global harmonisation. Lead to specialised Australia only product. Overseas manufacturers will require the sponsor to overlabel increasing costs and would be prone to error. The lag between product label development and ARTG numbers leads to increased costs in artwork. 12 months is too short a transition period. ARTG numbers are already available through the National Product catalogue. As part of 3 (i) enhancing eBS search facilities could address TGA's concerns.
68	Stryker Australia	Average Australian sponsor would not have the technology or systems to support this proposal. Would increase costs. Proposal 1 and 3 (i) will deliver this with the addition of a public search engine to allow the user to identify the ARTG number or alternatively the user could contact the sponsor.
69	STS Health	Overall support. Concerned that the increase in compliance costs will result in large one off charges and significant ongoing costs. Would require sponsors to open, apply labels and repackage the products leading to increased costs or special manufacturing runs may be required. Proposed transition times are too short.
70	N/A	N/A
71	The Pharmacy Guild of Australia	Supports and would like to also see a campaign to increase consumer and health care professional awareness of the ARTG number and where to find the information. Would support adding the ARTG number to the instructions as an addition not an alternative as there is a greater risk of losing instructions.
72	TrioDent Ltd	Space on many of the pack sis small and would result in Australia only packaging and would lead to added costs to the health care professional and consumer. Results in a very large one off cost and significant ongoing costs.
73	WelchAllyn	Parallel importing will cause confusion. Increased costs will be incurred by having to manufacture Australian and sponsor only products. If sponsor is required to do it would increase costs substantially. If 3(i) proceeds and an increased search function added to the ARTG this would negate requiring 3 (ii).
74	Whiteley Corporation Pty Ltd	No comment.

75	William Green Pty Ltd	Unclear what the requirements are. Is of concern as it would require Australian only production runs. Request transition time of 3 years. Results in a very large one off cost and significant ongoing costs.
76	Zimmer Pty Ltd	What is the definition of model? How can models be grouped or split? Transition time too short. Propose fee free updating during the transition period. What will the fee structure be? Propose TGA provide specific guidelines to advise industry on the level of information required.
77	Zoono Solutions Pty Ltd	Propose to either use GTIN numbers or align the eBS with the National Product Catalogue.

Proposal 4

#	Respondent	Response
1	3M Australia Pty Ltd	Supports publication of higher risk devices such as Class III and AIMD- not lower classes. Does not support publication of information relating to rejected applications. This process does not apply to prescription and OTC medicines and information would be considered to be corporate and of no benefit to consumers.
2	Abbott Australasia P/L (Diagnostics Division)	Does not support. Not clear how this would benefit end users. It is a duplication of information on the TGA website. This would act as a default assessment and approval process for each new model and device not currently requiring mandatory pre-market assessment. Publication of safety and performance data only on assessed product is of little benefit for other devices under the 'kind of device' and singles out medical devices.
3	Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)	Does not support particularly for lower classes. Believe the TGA should consider the types of devices that are likely to deliver benefits. Will lead to an increase in costs to industry. Do not support the publication of rejected applications. Do not see the value and believe it has the potential to confuse and undermine consumer confidence in individual sponsors unnecessarily as the product would not be available anyway.
4	Advanced Medical Technology Association (AdvaMed)	Supports Medical Technology Association of Australia (MTAA) position.
5	Amgen Australia	Only for high risk devices. TGA should be the author and could include: submission evidence; instructions for use; risk/benefit; and TGA's overall assessment. All rejected applications should be published as a source of information to guide new device applications.

6	AMPAC Dental Pty Ltd	No comment.
7	ANZ dental	No comment.
8	AusBiotech Ltd	Supports the principle. Raises further issues: who maintains the data: controls over the level of appropriate information consistent with the user profile; compliance with advertising standards; consideration about whether to publish information on rejected applications and whether this applies to all devices or higher risk devices only; and disclosure of commercially sensitive information and measures available to protect sensitive information?
9	Australian Dental Association Inc (ADA)	Supports for higher risk devices not lower risk devices. Will greatly increase costs as most of the material is produced overseas and will require review, editing, and legal checks.
10	Australian Dental Industry Association Inc (ADIA)	Not supported in its current form as it will add significantly to the regulatory compliance costs and hence consumers. Further the TGA has not demonstrated that it is in the public interest to publish this information. ADIA does support publication of information for Class III and AIMDs. Doesn't support publication of any rejected applications.
11	Australian Health Insurance Association (AHIA)	Support- The National Product Catalogue should be used to capture device details across industry.
12	Australian Orthopaedic Association Limited	Agrees with the approach as they are outlined in the proposal.
13	Baxter Healthcare Pty Limited	Supports for higher risk devices Class IIb, III and AIMD only.
14	BIOTRONIK AUSTRALIA PTY LTD Australia Pty Ltd	No comment.
15	BORG Dental (Bordent Pty Ltd)	Do not support. Is impractical as the medical model is not available for this sector. The dental professional has access to this data already. Leads to an increased requirement for information and duplication of current information. Questions who is responsible for maintaining the information.
16	Bosco Medical Australia	Do not see the requirement. Information is already freely available from the sponsor. Questions who would bear the cost of uploading the information and keeping it up to date? Information could be more regularly updated in house.
17	Bourke Dental Supplies	Do not support. Impractical to implement. No model for CMI or PMIs for this industry sector. Already have access to MSDS data, explanatory notes, web access and product information on line and through their professional body the Australian Dental Association.

18	CareFusion Australia & New Zealand	This proposal is of good intent. Difficult to keep the TGA website up to date. Confuse users as there will be two sources of information. Only credible source should be the manufacturer either on their website or provided to users directly. Publishing rejected applications does not add value.
19	Carl Zeiss Vision	No comment.
20	ConMed Corporation	No evidence that the existing information is deficient. Delays will be experienced if TGA needs to agree material. Concerned that commercially sensitive information would be publically available. May cause overseas manufacturers to stop supply in Australia or at least until available in other markets. Suggest limiting the required information to existing labelling and continue to use FOI provisions.
21	Consumers Health Forum of Australia (CHF)	Supports the publishing of: • General announcements of device approvals; • Copies of approval letters; • Summary of safety and effectiveness data; • Instructions for use; • Consumer instructions; and • Links to general resource information, such as information from the National Institute of Health (NIH) information or clinical papers.
22	Cosmetic Physicians Society of Australasia Inc	No comment.
23	Critical Dental Pty Limited	No comment.
24	Dentalife Pty Ltd	Strongly support. Will increase transparency of the TGA regulatory approval for medical devices and enhance identification to legally supplied approved medical devices.
25	Dentaurum Australia Pty Limited	No comment.
26	Dentsply (Australia) Pty Ltd	Most of the dental services that Dentsply (Australia) Pty Ltd supply are manufactured overseas so this would increase compliance costs for low risk devices. If the TGA publishes rejected applications information it would need to be limited to reasons of safety and/or efficacy similar to medicines. Publication of rejected lower risk devices for incorrect GMDN code or apparent GMDN code definition and intended purpose of a device would not be in the public interest.
27	Department of Innovation, Industry, Science and Research	Not enough information to fully assess the proposal. Suggest that this could be done by notification only.

28	Device Technologies Australia Pty Ltd	Does not support. Recommends: the need and specific benefits be clearly determined; this proposal should not be mandatory; and further discussion with stakeholders should occur. Agrees that information about assessments be published but not including the device literature and that TGA publish information about the decisions made during the assessment process but not rejected applications.
29	Draeger Medical Australia Pty Ltd	Do not see any increased value in doing this. Information is already supplied in the accompanying instructions for use. Users only interested in knowing if the device is TGA approved.
30	Dynek Pty Ltd	The proposal bears no relationship with Recommendation 8 of the HTA review. What is unclear is who will cover the time and expense in preparing, updating and validating these documents.
31	EBR Regulatory Affairs Consultants	It should be done at the expense of TGA.
32	ErskineDental	Support for higher risk devices but not lower risk devices. Increased costs would outweigh the need.
33	Essology Pty Ltd	No comment.
34	Fisher & Paykel Healthcare Limited	Unclear how this will benefit stakeholders and reject. Increased costs to manufacturers, distributors and sponsors. The value of publishing rejected applications is minor but potentially harmful to the manufacturer. Minor reasons such as incorrect GMDN alignment are not helpful. There is commercial sensitivity as it indicates an intention to a competitor to bring a new product to market.
35	GE Health Care Australia Pty Ltd	Supports. However cautions that publishing rejected applications may contain commercially sensitive material and may cause a manufacturer to reconsider submission. This may not be relevant to the consumer and healthcare professional.
36	GlaxoSmithKline Australia Pty Ltd	Does not support for all medical devices. Should be risk based. Higher risk devices only such as Class III and AIMDs. Lower risk devices should be exempted.
37	Gunz Dental Pty Ltd	Totally impractical. Dental professionals already have access to significant MSDS data, explanatory notes, web access and product information and supported by the professional body Australian Dental Association. Leads to an increase and duplication in information. Who is responsible for maintaining and ensuring its accuracy? No public interest on publishing rejected applications.
38	Healthlinks.net Pty Ltd	Support for all medical devices to be aligned as much as practical with that required for medicines. Suggest establishing usability guidelines for devices. Also suggests the distribution of the information expanded as much as possible. All information should remain copyright of the respective sponsor and all accuracy and currency of the information remain the sponsors responsibility.
39	Henry Schein Halas	Not supported in its current form as it will add significantly to the regulatory compliance costs and hence

		consumers. Further the TGA has not demonstrated that it is in the public interest to publish this information. ADIA does support publication of information for Class III and AIMDs. Doesn't support publication of any rejected applications.
40	Independent Rehabilitation Suppliers Association (IRSA)	No comment.
41	Integra Neurosciences Pty Ltd	No comment.
42	Invacare Australia Pty Ltd	No comment.
43	IVD Australia	Not supported. Require information on what material is required, how it is initially to be entered and who will update it. Recommends that only successful applications that have undergone a mandatory application audit should be published and that rejected applications not be reported. Suggests duplication of already existing materials.
44	Ivoclar Vivadent Pty Ltd	No comment.
45	Johnson & Johnson Medical Pty Ltd	Supports for higher risk devices only (class III and AIMDs) and to devices where the end user is a patient. Information is already provided via company websites and booklets and recommends that accessibility be enhanced through collaboration with industry associations such as the Medical Technology Association of Australia (MTAA). Do not support publication of information which is intended solely for the user (health care professional) and may contain proprietary information. Do not support the publication of rejected applications due to commercial in confidence reasons. Recommend that TGA publish a percentage of applications rejected versus those approved as a measure of effectiveness.
46	Johnson & Johnson Pacific and Vision Care Australia	Should be risk based. Higher risk devices only such as Class III and AIMDs. Lower risk devices should be exempted as information that would be published would not have been validated.
47	Magic Mobility (Red Milawa Pty Ltd)	No comment.
48	MAQUET Australia Pty Ltd	Patient instructions, IFU's, user guides, references to clinical papers are typically available on the manufacturer's website. Would require significant commitment to keep up to date.
49	Max Boccardo Associates	Support for Class III devices and higher but not lower.
50	Medical Technology Association of Australia (MTAA)	Recommends that the publication of device information on TGA's website be trialled on a small scale, voluntary pilot with implementation on a broader scale only after positive assessment of the pilot including consumer

		support.
51	Medtronic Australasia Pty Ltd	Proposes that this be subject of a separate consultation process to examine the real need being addressed, the kinds of information already available and the medium to be used to supply the information.
52	Multigate Medical Products Pty Ltd	Should be restricted to higher risk devices such as Class III and AIMD as the cost for providing information for lower risk devices does not offset the public gain.
53	National Serological Reference Laboratory (NRL)	Support the TGA including on its website the depth of information similar to that published by NRL for IVDs. NRL suggest that this could be directly linked. It is unclear if the TGA will seek approval from manufacturers or sponsors prior to publication nor wether the TGA will set criteria for publication of such material. Manufacturers or sponsors may be reluctant to have material published even if the material is largely positive. It is also unclear how the TGA will treat applications that are withdrawn by the sponsor/manufacturer if the NRL recommends against an IVDs inclusion on the ARTG.
54	Nobel Biocare Australia Pty Ltd	May create confusion as the public may not understand the information, increase business costs to provide the material, feel that there is no benefit in publishing rejected applications. Will lead to a large one off cost and significant ongoing costs. Recommend a 2-3 year transition time.
55	Novo Nordisk Pharmaceuticals Pty Ltd	For lower risk devices agrees to publish user instructions on the TGA website with responsibility lying with the sponsor. Does not see significant public benefit in any other information described being made available on the website.
56	NuVasive Australia & NZ Pty Ltd	Supports in part. Support for Class III devices and higher but not lower and only for information on approvals. Should not publish commercial in confidence material such as unpublished clinical trial data. Responsibility of authorship should be with the TGA however the sponsor must be consulted to review the proposed information. TGA should also be responsible for maintaining the information. Rejected applications should not be published. Making instructions for use publicly available will result in additional burdens on the medical devices industry and is also unnecessary given the information is already supplied to users.
57	Otto Bock Australia Pty Ltd	No comment.
58	Paragon Therapeutic Technologies Pty Ltd (PTT)	IPUs are generated by the TGA as part of the evaluation process for medicines and therefore a TGA document to place on the web. TGA does not approve IFUs or manuals for a device during the review process. Believes it provides no essential value, could cause confusion and the information is already available on the company websites. Concerns that this will create unnecessary high administrative overheads. Many medical devices are exclusively produced for healthcare practitioners and the information provided is tailored to them and see no use supplying this information to the patient. Many items are obvious as to their use and do not need an IFU and for some instructions are on the pack. If 3 (i) proceeds it would be possible to access the information through the

		internet.
59	Pfizer Australia Pty Ltd	Support for Class III and AIMDs and possibly only for those that have undergone Conformity Assessment by the TGA. The TGA should be responsible for authorship only if the documents relate to the decision making process. Do not support publishing of rejected applications as this may be taken out of context. The maintenance of substantial product information type documents is onerous especially for smaller Australian based manufacturers. Consider the manufacturer should be responsible for providing this information and the stakeholder responsible for the risk analysis. If a PI is considered necessary by stakeholders it should only be for higher risk medical devices. Suggest that IFUs could be provided by company websites as an alternative.
60	Queensland Health- Clinical and Statewide Services Division	No comment.
61	Queensland Health– Chief Health Officer	Support. There is a great opportunity to inform consumers and healthcare facilities about the latest developments, product performance. This could be supported by jurisdiction/facility product procurement and medical device review groups. Align with the National Product Catalogue.
62	Queensland Health– Centre for Healthcare Improvement	Fully support. Would be of great benefit to a consumer organisation such as Qld Health. It should include all devices. Should include information such as that on the FDA website, links between ARTG products that are used in combination or in a system, service manuals, amendments, relevant dates ie end dates, recalls, suspended, removed or withdrawn entry, relevant history of sponsor, manufacturer and distributor changes and the identity and address of official distributors. Manufacturer and sponsor should be responsible for the maintenance except for recalls etc. Can see limited benefit in publishing rejection decisions unless the product is not a therapeutic good, or the product is still supplied in Australia, or for providing advice to a consumer organisation for replacement of the device. This information would be beneficial if an application is made to an ethics committee for a clinical trial or for the special access scheme.
63	Resmed	Oppose for Class IIb and below as the requirement would act as a default assessment process. Information is already available through the distribution network or online. Information required for higher risk devices should be limited to what is already required in the application audit.
64	Royal Australasian College of Physicians (RACP)	No comment.
65	RTI Biologics Inc	Generally support for product summary information regarding safety and effectiveness of higher risk devices such as Class III and AIMD. Recommend information authored by the manufacturer, if authored by the TGA the manufacturer should be able to review prior to publication to allow protection of proprietary information. TGA

		establish a system for timely updates by the manufacturer and further information should not be required until this system is established. Against posting device labelling on the TGA website and having two competing sources of information. Oppose disclosure of rejected applications. Could be detrimental to companies and new improved products.
66	Seating Dynamics Australia Pty Ltd	No comment.
67	Smith & Nephew Pty Ltd	Evidence is required for the need for this information. Needs further consultation.
68	Stryker Australia	Would create confusion and duplication as material is already available on the company website. The effort involved for sponsors/manufacturers to update this information would be a vast undertaking.TGA should examine the information captured during the application and review what data is made available on the public summary for each ARTG.
69	STS Health	Concerned at the depth of information required and will the TGA have a surveillance unit that verifies the information?
70	N/A	N/A
71	The Pharmacy Guild of Australia	Support. Would like information sheets for all medical devices that can be readily accessed by consumers and health care professionals. The information must be of use and its preparation should not be onerous. Should include: ARTG number; Device/product type; brand name; model number/s; classification level; Australian sponsor and contact details; information about correct use; information about maintenance (where relevant); and information about separate parts or consumables (where relevant). Suggest a TGA campaign to educate consumers and health care professionals about TGA operations and related regulatory matters and resources.
72	TrioDent Ltd	No comment.
73	WelchAllyn	Information supplied should be a direct correlation to the information supplied for the device application. Do not support publication of rejected applications.
74	Whiteley Corporation Pty Ltd	No issue with publishing all material so long as full formulation details are not required for chemical products, only ingredients that are required for compliance with hazardous substances, scheduled substances and dangerous goods. For disinfectants the active ingredient should be listed. Responsibility for authoring and keeping up to date should lie with the sponsor/manufacturer. Rejected applications should not be published.
75	William Green Pty Ltd	Support for higher risk devices not low risk. Results in a very large one off cost and significant ongoing costs.

76	Zimmer Pty Ltd	Propose TGA only publish information for consumer products. Could publish: Device and application information; intended use; indications; instruction for use; warnings and precautions; contraindications; and care of the product. No public health benefit in disclosing rejected applications.
77	Zoono Solutions Pty Ltd	Propose to either use GTIN numbers or align the eBS with the National Product Catalogue.