Letter from Dr Matthew Athanassiadis

By MATTHEW ATHANASSIADIS

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Dear Sir,

I am one of those ADA members who chose to speak to the media in support of the right for the Australian public to know where their crown and bridge work is being fabricated.

It is unhelpful when there are inaccuracies regarding this issue communicated by the Federal ADA and the ADAQ.

To begin with, our federal President, Shane Fryer, states in a press release dated 6th of July 2011 that:

“Dentists are required to ensure that custom-made dental prostheses or appliances made overseas comply with the Therapeutic Goods (Medical Devices) Regulations 2002 (TGR 2002) and are listed on the Australian Register of Therapeutic Goods (ARTG).”

This is incorrect. Custom-made therapeutic goods are NOT listed on the ARTG register (Australian Regulatory Guidance for Medical Devices V1.1 May 2011 Page 249). It would be impossible to have every crown fabricated listed on the ARTG register.

Additionally, in the ADAQ, there were many statements made which were not accurate. Firstly, it is incorrect to suggest that crown and bridge work are not regulated by the TGA. Crown and bridge work are regulated as custom-made medical devices by the TGA (Part 7 of Schedule 3 of the Therapeutic Goods Act 2002). The problem, however, lies in that TGA do not audit or place any significant requirements on custom-made medical devices other than a one-page declaration from the importer stating compliance with TGA’s “Essential Principles”. There is no requirement of proof of compliance from the TGA and no audits are performed, which differs markedly from all other medical devices with similar characteristics. For example, filling materials are Class IIa medical devices and require auditing, surveillance, proof of conformity with the essential principles (primarily through ISO 13485:2003) and are issued Conformity Assessment Certificates by the TGA listed on the online ARTG register.

Custom-made medical devices are not issued conformity assessment certificates and are not audited by the TGA. They do not require ISO 13485:2003 and they cannot be viewed on the ARTG register. It becomes obvious that the requirements are far less. The reason for this difference is that, in the past, custom-made medical devices were alterations to existing medical devices. These were considered one-offs for special circumstances where conformity assessment was not possible. For example, if you required a hip prosthesis to be modified for a particular patient, and if the standard procedures were in place and a conformity assessment were required, then it would take over 12 months to gain the approval and several tens of thousands of dollars for each single device. This is unworkable. Crown and bridge work, as the regulations stand, falls into this loophole.

Australia and Europe have a harmonised regulatory system in place for medical devices allowing for an easier way for products from Europe to come to Australia and vice versa. When products undergo a successful conformity assessment for Europe, they are issued a CE certificate. Interestingly, European Competent Authorities are not required to accept CE certificates on goods manufactured outside of Europe and Australia and TGA do not accept CE certificates on goods manufactured outside of Europe. The reason for this is that in many cases the certificates are issued by private companies and not competent authorities like the TGA.

Crown and bridge work performed outside of Australia is outside the control of the Australian Regulatory System. Quality cannot be assured by the issuing of certification from notified bodies whose auditing does not consider Australian requirements. ISO 13485:2003 does not guarantee a quality product for Australia if the issuing of the certification is not from an Australian Competent Authority – namely – the TGA. And since the TGA is not required under law to audit overseas laboratories, along with the loophole which exists for custom-made medical devices, quality crown and bridge work, sourced from overseas, cannot be guaranteed.

It is important for dentists to think about how overseas crowns can be supplied so cheaply. A typical overseas-made crown may vary in cost from $20 to $30 dollars if purchased directly from the overseas laboratory rather than a middle man in Australia. If the mark-up from that laboratory was, say $10, then you would have the cost of manufacture of the crown, including labour, at $10-$20. For this reason there have to be legitimate concerns regarding the quality of the work and materials supplied. Obviously, distribution centres who send literally hundreds of crowns per day to these overseas laboratories can extract better deals and so the cost to them may conceivably be even lower. The mark-up from distribution centres can be approximately calculated from these figures and would be in the 300%-600% range.

No local laboratory can produce a crown for that price. The cost in materials alone would far exceed the retail price of overseas-made crowns to the dentist. This is not a level playing field. This is not about keeping the technicians honest so they do not overcharge. This is about destroying the whole dental technician industry in Australia for the short term benefit of a few without even considering the quality of the product supplied and its impact on patients.

Recently, I have received emails from distribution centres who, as proof of quality, state their ISO certification. They have quoted, for example, ISO 9001:2003 and ISO 13485:2008. It all reads impressively but when you perform due diligence you find that ISO 9001 does not apply at all to medical devices and is not accepted by TGA as demonstrating compliance with the essential principles. In addition, ISO 9001:2003 does not exist. ISO 9001:2008 is the correct standard. Similarly, ISO 13485:2008 does not exist. The correct standard is Iso 13485:2003. The next update for ISO 13485 is in 2015. One has to question the sincerity of the commitment to quality if neither the appropriate nor the relevant ISO certifications can be quoted.

The only way to ensure that a product imported into Australia complies with the relevant standards is to have a fully audited process performed by the TGA which stipulates and checks that the correct materials and processes are utilised. This is not occurring.

Local technicians have their materials regulated in that they must use materials that the TGA has both approved and classified as medical devices (e.g. porcelain blocks) or with

ingredients that the TGA accepts as being safe to use. So, even without ISO certification by local dental laboratories, the fact remains that Australian-made crowns are of better quality in that regard.

Irrespective of the above, one must respect the right of the dentist to purchase overseas- made crowns. There is nothing illegal about this practice. However, patients should also have the right to know the origin of their crowns. The reason for this is that many of the countries from which crowns are imported have had issues in the past with their manufacturing practices. For example, there have been cases of poisoned baby's milk, lead painted children's toys, poisoned tooth paste, poisoned eggs to name but a few and most of these were produced under "ISO certification". There is evidence of false CE certification, the use of CE as "China Electronics", etc. In an unregulated world, there are greater risks and as health professionals the onus is more and more being placed on us to make an assessment of these risks. The reality is that we simply do not understand all the regulations and ISO certifications, and not just in what they mean but also in their limitations in being able to guarantee quality. On this basis, how do we then as dentists justifiably make the decision on behalf of the patient when we have insufficient knowledge and information?

To sacrifice our dental technician industry for the sake of short term gain cannot be justified. Once the local industry has disappeared then you can be certain that the imported costs will rise. To destroy such a valuable building block of dentistry, to make education centres redundant and to take away all the expertise, etc. for the sake of short-term easy profit is a bad call.

All the talk about the risk of dental tourism, where patients travel overseas to have dental treatment performed at cheaper rates, applies almost entirely to the current situation involving crown and bridge work. We certainly risk looking hypocritical if we caution against one and yet have no problem with the other.

So, what is the solution? It can vary from the most complex to the straightforward. The easiest option would be to make certification for each crown mandatory. A certificate in triplicate is issued by the laboratory containing the following information: the physical location of manufacture, the ingredients used and the name of the technician who did the work. This certificate would then be signed by the dentist and given to the patient. In this way, the process is transparent and can also be used as an audit trail in case of problems or recalls.

The issue of overseas-sourced crown and bridge work is complex. There are no ADA courses for anyone to attend in order to gain a better understanding and maybe the ADA can do something to rectify this. There is a certain enlightenment that comes with understanding the whole regulatory framework and it allows for members of our profession to make better judgements in relation to quality and safety. Above all, it lets us make sense of the incessant spin and financial speak which tends to dominate so much of dentistry today and, in doing so, safeguard the standard of dentistry delivered to patients.

Dr Matthew Athanassiadis