SEARCHING FOR AN EVEN PLAYING FIELD

A call to government to assist Australian medical innovation

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November 2016

ABSTRACT

The Australian Government has launched an 'innovation agenda' that aims to encourage Australian advanced manufacturing, job creation and exports. Unfortunately, when it comes to Australian medical manufacturing the biggest barriers facing Australian companies are those constructed by the Australian Government in the last century.

The advent of advanced manufacturing techniques such as 3D printing or additive manufacturing, has made viable the concept of a "patient-specific" surgical implant, designed and fabricated, on demand, to fit one person only. This concept unfortunately does not fit the paradigm of a comprehensively tested and validated medical device, which our regulatory system has been designed around.

This inability to gain regulatory approval for patient specific implants, leads to an inability to gain reimbursement from health insurance companies via any other pathway than case-by-case negotiation, a cumbersome, costly and ineffective process.

The gap in our regulatory system must be addressed if Australian device manufacturers are to flourish in accordance with the government's innovation agenda. Australia already imports almost all medical devices and prosthetics, and has an unsustainable private healthcare system that requires insurers to pay a 40% premium on imported products compared to other OECD countries.

Australian industry has the skills and facilities required to capitalize on the revolution in personalised healthcare. With adequate government support, we will be able to continue growing, creating jobs, affording our local healthcare providers access to vastly more cost-effective prostheses, and dramatically reducing the environmental footprint of the surgical prosthetic manufacturing and logistics industry.

PREAMBLE

In December 2015 the Australian Federal Government launched its National Innovation & Science Agenda policy with the aim of encouraging Australian advanced manufacturing, job creation and exports. Oversight of this agenda was vested in the newly established body Innovation Australia (IA), chaired by Bill Ferris AO and Chief Scientist Alan Finkel. The IA board held its first meeting in September 2016 in the wake of the July 2016 federal election. The innovation policy had been a showpiece of the election campaign.

There is no doubt about the "why": Australia needs innovation. It is the "how?" that has yet to dispel the doubters. And in this context, it is the domestic medical device industry

that is asking "how" against a backdrop of apparent government and bureaucratic unwillingness.

What is urgently required to advance Australian medical manufacturing – and spur the shift to a major plank in a sustainable healthcare system – is the removal of a the 40 per cent premium (compared to other OECD countries) that is levied by medical insurers on imported prostheses, medical implants and wearables.

This is punitive on the medical insurance industry, on medical and surgical practitioners and on patients and, thereby, patient outcomes. This situation favours multinational enterprises. It allows them to harvest lucrative profits and carry these offshore while paying little or no Australian domestic tax.

On such an uneven playing field the Australian Government cannot reasonably expect Australian medical manufacturing companies to competitively innovate, create jobs, manufacture and export. The first question asked of any Australian medical manufacturer promoting their technology overseas is: "Are your products reimbursed and viable in Australia?" The glaring answer is, generally, a firm "no".

This document outlines the bureaucracy that fetters efficient regulation of Australian medical device manufacturers.

THE CURRENT SITUATION

The Therapeutic Goods Administration (TGA)[1] recently secured funding to undertake a review of emerging technologies, and 3D printing of medical devices forms part of the review. There is currently no Australian regulatory or reimbursement framework for medical 3D printing, and no Australian hospital actively (or commercially) using this technology. As a direct consequence of this lack of regulation there are key issues surrounding medical insurance and the rebates available to publicly and privately insured patients requiring medical device surgery.

This means that there is no accelerated pathway for a small Australian device manufacturer who cannot afford to wait up to 18 months for a medical device to be registered on the Australian Register of Therapeutic Goods (ARTG).[2]

Such a pathway would allow the TGA to focus on post-market surveillance, auditing companies, post-ARTG inclusion, and reduce the cost for small Australian manufacturers trying to enter the Australian market. Currently, Europe, the US and Japan have accelerated pathways for devices that meet certain criteria.

There is no accelerated pathway for inclusion on the ARTG for innovative Australian manufacturers to allow "breakthrough" medical technologies to benefit Australian patients any sooner than those generated and manufactured overseas.

[1] The TGA is part of the Australian Government's Department of Health & Ageing and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

[2] The ARTG is the central point of control for the legal supply of therapeutic goods in Australia. Goods sponsors take responsibility for the supply of a medical device in, or from, Australia.

The TGA does not recognise overseas regulators as having a matching emphasis on safety, quality and efficiency. So, if a product is manufactured in an ISO-certified[3] environment and has been approved by a trusted overseas regulator, why doesn't the TGA accept such a product on to the ARTG following review of the regulators report? If an audit is required this could be carried out post-inclusion.

Australia has failed to harmonise its requirements with those of the European Union (EU) and the US Food & Drug Administration (FDA)[4], thereby increasing the time taken to develop new devices and leading to increased costs and time in preparing different dossiers for different regulators – for example, European Commission[5]/Australian design dossiers, classifications and essential requirements/principles.

Synchronisation with offshore health regulators and administrators would increase the speed to market for Australian manufacturers, allowing patients access to innovative therapies far more rapidly than is currently the case. Section 8 of the ARGMD[6] describes the differences between the Australian and EU medical device regulatory requirements. Specifically, it details medical devices that are classified differently in Australia and the EU, citing hip, knee and shoulder joint replacements. This raises the question as to why Australia's public servants insist upon "reinventing the wheel" in our smaller domestic market?

A conformity assessment audit ought to be sufficient evidence for the TGA to include a product on the ARTG. Instead, following a TGA audit of the manufacturing facility and product, an additional submission of a design dossier, and an 18-month wait, the TGA generates further questions about the product in a way that is overly taxing and prohibitively expensive.

In the US, a pre-market notification [510(k)][7] submission can be made to the FDA to demonstrate that a device to be marketed is safe and effective by proving substantial equivalence (SE) to a legally marketed device (predicate device) that is not subject to pre-market approval (PMA). This is not a possibility in Australia and leads to inordinately prolonged waiting times for ARTG inclusion.

In New Zealand, once a Class III [high risk] medical device has a CE symbol[8] it can be included on the WAND[9] database within NZ and sold immediately. This is not the case in

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[4] The FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human [and veterinary] drugs, biological products, and medical devices.
[5] The EC is the executive body of the EU responsible for proposing legislation, implementing decisions and upholding EU treaties.
[6] The Australian Regulatory Guidelines for Medical Devices is administered by the TGA. In collaboration with the medical devices industry the TGA developed a reference document detailing the Australian regulatory requirements for medical devices.
[7] A 510(k) is a pre-market submission made to the FDA to demonstrate that a device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device.
[8] The CE symbol is applied to products to indicate that they conform to the relevant EU directives regarding health and safety or environmental protection.
[9] Web Assisted Notification of Devices is a medical device notification database for NZ that facilitates the management of recalls and safety alerts.

Australia. Here, device manufacturers have to wait for public service adjudications on exhaustive submissions to the ARTG, and then undergo a mandatory application audit. This stalls the sale of products in Australia for a further 18 months and costs up to A$7000 per application.

Australian-manufactured Class III products can be registered (as mentioned above) in the US via a 510K submission within two months. Australian-manufactured Class III products can obtain a CE symbol in two to five months, by a notified body, for sale in Europe. But the same products cannot be sold in Australia due to the mandatory TGA audit that is required and can take up to 18 months at a cost of A$100 000.

To make matters even worse, Australian Class III applications have to undergo two clinical assessments conducted by different delegates (TGA and PLAC). Once a small Australian company has waited an inordinate length of time, paid fees and explained complex products to one delegate, the TGA, then burdens that company with a second review by a different delegate, PLAC who may be equally unfamiliar with the devices in question. Although Australian taxpayers may be able to withstand this bureaucratic process, small Australian medical manufacturers cannot.

Despite Australia having pioneered medical 3D printing more than 20 years ago, the current regulatory system still does not officially recognise this innovative technology. Nor does it offer reimbursement for patient-specific or bespoke devices and prosthetics. Instead, manufacturers and doctors must plead on a case-by-case basis to with medical insurance operatives, begging for "ex-gratia pre-approval" for patient-specific devices and prosthetics.

Insurers are not required to pay for these and often doctors and their patients are left in abeyance for months at a time. To meet the needs of patients unable to tolerate their pain and suffering any longer, surgeons are forced with no alternative but to use inferior, imported off-the-shelf products.
The Australian MSAC[10] and PLAC[11] advisory committees deliberate at length, and at taxpayers' expense, on the scientific evidence and virtue and cost-effectiveness of new technologies embodied in locally manufactured devices. The net result is that new medical technologies remain blocked from practical medical applications, and patient outcomes suffer under the status quo.

It is presumed that the government operates in the belief that this will keep a lid on healthcare costs. Yet this stance fails to accept that while expensive legacy therapies and devices are funded well past their use-by date, it costs taxpayers heavily and creates needless ongoing suffering for numerous Australian patients. The heavy emphasis on scientific evidence (a stance inherited from the machinations of the Pharmaceutical Benefits Scheme) is often needlessly brought to bear on innovative surgical procedures and devices with obvious benefit.

[10] The Medical Services Advisory Committee is the independent, non-statutory committee established by the Australian Government in 1998 to appraise new medical services proposed for public funding. It provides advice to government on whether new medical services should be publicly funded on an assessment of their comparative safety, clinical effectiveness, cost-effectiveness and total cost,

[11] The Prosthesis List Advisory Committee to provides recommendations to the Minister for Health & Ageing on the listing of products on Part A of the Prostheses List, and the benefits payable for them.

Having to prove the obvious to such an unattainable and possibly unethical level of statistical significance has made it prohibitively expensive for any Australian company to achieve device cost reimbursement within Australia. Unsurprisingly, this situation suits a coterie established multinational corporations; they can use their considerable financial clout to muscle their new technologies into the Australian healthcare system.

KEY CONSIDERATIONS FOR GOVERNMENT (AND HEALTH ADMINISTRATORS)

- Randomised, blinded prospective trials do *not* apply to medical devices and prosthetics?
- Personalised healthcare enabled by patient-specific 3D-printed medical devices does *not* allow randomised, prospective data to be collected because each individual treatment and/or device is singularly different.
- It is neither ethically nor scientifically necessary to continually have to prove the obvious medical efficacy of patient-specific devices beyond all reasonable benchmarks.
- The current prohibitive regulatory barriers are the main obstacle to the ongoing viability of Australian personalised healthcare providers.
- Given a truly government-led innovative agenda and accompanying policy Australia could be at the vanguard of community focused personalised healthcare domestically and overseas.

SUMMARY

If the Australian Government was true to its agenda of promoting Australian innovation and manufacturing it would accept that personalised healthcare is a fast-growing tide that inevitably requires a new regulatory framework.

If politicians of all persuasions harness the resolve to meet this head on they would champion the creation of a regulatory system allowing for a far more even playing field for Australian medical device manufacturers. This would enable the advance of Australian medical technology and create jobs domestically, and lead to the export of Australian-produced technologies.

Custom-made, 3D-printed patient-specific implants are more durable than their off-the-shelf counterparts, are longer-lasting and cheaper to produce than alternative implant offerings. They fit better, meaning fewer complications and better patient outcomes. They are innovative, but are costly across the consumption chain right down to the end recipient.

Any formal definition of innovation one cares to choose will refer to the translation of an idea or invention that creates value at a replicable economic cost, and that fulfils a specified need. The need exists. A lower calculable cost to patients is achievable. It appears that only government will is lacking.

ENDNOTE

The Federal Government's innovation agenda has been well telegraphed to the

Australian public.

In Victoria, the State Government is the benchmark around Australia for facilitating trade missions of Victorian industry to key international trade markets. It heavily promotes within Australia through industry attraction programs and company concessions, and internationally via its 20 trade offices around the world it promotes Victoria's sector strength in health and medical research and innovation. The promotion of this sector is a priority for the Victorian Government and has also been well disseminated publicly.

For Anatomics, as a company with a deep history in medical 3D printing, it openly acknowledges that both the Federal and Victorian Government agendas house the potential to be to its direct benefit.

But Anatomics further contends that given a workable Australian regulatory framework for medical 3D printing, and the ability for hospitals to actively utilise this technology, the benefits would flow to the industry at large and thereby to personalised healthcare.

For its part, Anatomics is in the process of seeking to secure collaboration with St Vincent's Healthcare in Melbourne to establish a medical 3D printing "Solutions Centre" within an Australian hospital. If successful, this would be the precursor to a clinical trial framework and, ultimately, securing TGA interim approval. This fits the Federal Government's innovation agenda/policy. And given success within a proven clinical environment in Australia, the flow-on effect would be to export the technology or "solutions centre" concept overseas after demonstrating its viability in Australia.

Anatomics is well-placed and willing to partner with government – working with the TGA and CSIRO – not only in championing innovation but assisting the TGA to advance its status in being a world-leading regulatory body.

Following discussions with Federal Government and Victorian State Governments the feedback indicates that there is significant goodwill towards working collaboratively with Anatomics.