Medical Technology Association of Australia

Submission to Strategic Review of Health and Medical Research

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

1. Executive summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the key questions identified by the expert panel established to advise the Strategic Review of Health and Medical Research (McKeon Review).

In this submission MTAA has focused on those questions asked by the McKeon Review which are directed to improving the more effective translation of Australia's health and medical research. MTAA believes that Australia's excellent capability in research does not lead consistently to the growth of innovative businesses which can take the results of that research to market. There are systemic reasons for this, including the lack of policy at a national and state level that values the role of innovative industry and treats industry as a partner in the healthcare system.

A strong health and medical research sector provides the supporting framework for innovation in health care to meet Australia's health needs. It can also provide the genesis of a strong Australian medical technology, and broader life sciences, industry. A strong Australian industry will not only meet the needs of Australian patients in the future but be a catalyst for a skilled manufacturing industry with export potential.

2. About the Medical Technology Association of Australia

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, to diagnostic imaging and operating theatre equipment, to products which incorporate biological materials or nanomaterials.

MTAA represents companies which account for approximately 75% of products listed on the Australian Register of Therapeutic Goods (ARTG). The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small and medium sized Australian innovator companies.

3. What are the health and medical research strategic directions and how might we meet them?

This submission focuses on the steps from research to market which are core to nurturing a vibrant medical technology, and broader life sciences, sector. These steps include access to clinical trials (clinical evaluations in the case of medical technology), access to adequate funding, and mechanisms to assist with market access.

Australia is a good location for clinical trials at any stage. Clinical trials are worth around $1 billion to the Australian economy each year (including approximately $450 million in foreign investment)[1]. There was rapid growth in the number of clinical trials being conducted in Australia from the early 1990s, however this growth hit a plateau and has started a downward trend in the last few years.

Australia faces increasing competition from countries in regions such as Asia, South America and Eastern Europe which can run clinical trials at a lower cost and have more volunteers. Costs and delays in gaining ethical approval may have also influenced a decline in Australia's competitiveness in this area. In March 2011 the Australian Government accepted the recommendations of the Clinical Trials Action Group which, it is hoped, will improve the speed of approval for new trials and streamline a national ethics approval process.

An Australian survey has addressed the value Australia derives from industry funded clinical research[2]. Survey respondents reported involvement in a total of 3,484 clinical trials and research projects, of which industry was the major funder. Six key categories were rated high or very high value by the majority of respondents: early access to medicines and improved outcomes; translation of evidence into clinical practice; enhancing Australian trial expertise; enhancing the global profile and research opportunities for researchers; provision of funding for research and academic projects; and retaining researchers in the public health system.

Smaller Australian enterprises are often disadvantaged in generating clinical trial data because of lack of access within the public health system to facilities, medical professionals and patients. Further trials could be enabled through specific policies which provide dedicated access for technologies which indicate potential at the research phase.

In order to translate research which is successful in clinical evaluations into viable products for a health market there is a need to support the development of prototype products at the critical early commercialisation stage. An option to address this is the establishment of a Medical Device Fund which would be tasked

[1] Australian Government. Clinically competitive: Boosting the business of clinical trials in Australia. Clinical Trials Action Group Report, 2011.
[2] Bourgeois, C. (2008). Value of Industry Sponsored Clinical Trials in Australia. Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research. NSW Clinical Trials Business Development Centre, on behalf of the Pharmaceuticals Industry Council (PIC).

with linking people, processes and investments, particularly targeted at small and emerging companies in the industry. The fund would operate by supporting innovations which respond to priority health needs. It can provide key financial and expert technical assistance to companies when a working prototype is being developed.

Areas of assistance should be designed to ensure companies are well versed in regulatory affairs, quality management, and reimbursement and that they have access to clinical investigations and access to local manufacturing. The fund could also offer training on customer needs before the product gets to the design and investor stage which should achieve a higher success rate of commercial product than we have seen in Australia to date.

The Medical Device Fund should work closely with government by leveraging existing government programs as appropriate such as those currently offered by Commercialisation Australia. There are other partnering programs which support early stage commercialisation through the provision of specific skills and advice including the Medical Device Partnering Program at Flinders University in South Australia, which receives funding from the SA Government.

Access to finance is one of the greatest challenges for emerging companies. An option which has been used in other countries is for government to act as guarantor for funds provided to small companies which otherwise would have limited access to finance to undertake further product development and enter the market. For example, under Canada's small business financing program, the government guarantees 85% of eligible small business loans for a small fee which makes the scheme self financing.

More creative thinking needs to be applied to the establishment of venture capital funds which can be dedicated to funding medical technology innovation. A good example is the Pennsylvania Life Sciences Greenhouse (PLSG) based in Pittsburgh the US, which was founded as a public/private partnership in 2001 by the Commonwealth of Pennsylvania, University of Pittsburgh, Carnegie Mellon University, University of Pittsburgh Medical Center and Pittsburgh's regional foundation community. Its mission is to foster the development of a research and economic community that will put Pittsburgh at the forefront of the life sciences industry and accelerate the introduction of biomedical innovations to the marketplace.

In February 2012 PLSG announced that it had completed a further capital-raising of more than US$8 million to invest in local medical device and diagnostic companies.

The reduction in angel investment following the global financial crisis prompted the province of Ontario, Canada, to start a C$40 million government-backed venture capital funding initiative. The government has recognised that R&D tax credits assist going concern companies but less so start-up companies. The government in Ontario is refocusing from research and development to translation and

commercialisation and direct investment funding. The Ontario Centres of Excellence program draws funding from provincial and federal governments, matched with industry funds.

Another program in Ontario aimed at supporting the medical technology industry is the Healthcare Technology Exchange (HTX), a federal and Ontario government-funded organisation that aims to support the research and development of advanced healthcare technologies. HTX manages a C$21.4 million budget provided by the Ontario Ministry of Economic Development Innovation to help SMEs and start-ups to get funding to reach domestic and global markets, and to attract multinationals to set up research and development in Ontario.

4. How can we optimise translation of health and medical research into better health and wellbeing?

In a recent white paper[3], MTAA argues that there needs to be better integration between health system needs and industry development. Through collaboration between heath and medical researchers, health policy leaders, and the life sciences industry, there can be an improved understanding of health priorities to which the industry can respond.

Other countries with similar healthcare systems and healthcare challenges have addressed similar objectives. Governments in the United Kingdom over the past decade have instituted a range of policies to stimulate development of the life sciences industry in that country. In April 2009 the government established the Office of Life Sciences to co-ordinate national policy work to build a sustainable and integrated life sciences industry. Among its objectives was to consider how the National Health Services (NHS) could be more effective as a champion of innovation, how the United Kingdom could become a more attractive base for clinical trials, and how the life sciences industry could be marketed globally more effectively.

The Office for Life Science published a Blueprint in July 2009[4], the purpose of which was to accelerate the uptake of technologies from UK firms. The Blueprint had the stated aim of transforming the UK environment for life sciences companies and to ensure faster patient access to cutting edge medicines and technologies.

The strategies outlined in the Blueprint include a requirement that NHS review system levers and incentives to accelerate the uptake of medical technologies. The government supported the formation of a UK Life Sciences Super Cluster to co-ordinate work across industry, higher education and the NHS and to boost international recognition of UK life sciences. Through the Technology Strategy Board (TSB) it also launched an £18 million 'RegenMed' program of investment to support

[3] Medical Technology Association of Australia, *Building a Sustainable Medical Technology Industry for Australia*, Sydney March 2012

[4] http://www.dius.gov.uk/innovation/business_support/~/media/publications/O/ols-blueprint accessed 16 July 2009

commercial R&D with additional funding from the Medical Research Council, the Engineering and Physical Sciences Research Council, and the Biotechnology and Biological Research Council.

The UK government describes the strategy as placing innovation at the heart of healthcare delivery as well as supporting the country's knowledge industries. The Blueprint is part of *Building Britain's Future*.

In December 2011 Prime Minister Cameron presented the Strategy for UK Life Sciences[5] (SLS) to further the work of previous programs. The SLS is a wide-ranging strategy based on three key principles:

- Building a life sciences ecosystem
- Attracting, developing and rewarding the best talent
- Overcoming barriers and creating incentives for the promotion of health care innovation.

The strategy aims to cultivate investment that pushes innovative UK medtech development and production to the global marketplace. In parallel with the SLS the NHS released its review of innovation in December 2011[6] with the aim of accelerating adoption and diffusion of innovation within the UK health system.

The NHS innovation review provides an excellent roadmap for the integration of health system need with facilitation of industry development. The review identifies four ways in which the NHS contributes to the UK economy. Importantly these include the support it provides to the life sciences industry by accelerating adoption and diffusion of innovation. By exporting innovation, ideas and expertise, working in partnership with UK industry, it also provides new business opportunities overseas for UK-based companies[7].

The approach taken by the report is that the NHS is a major investor and wealth creator in the UK, and in science, technology and engineering in particular. NHS success in adopting innovation helps support growth in the life sciences industries which in turn enables the industries to invest in developing the technology which the NHS needs[8].

Among the agreed actions are:

- Automatic adoption of all NICE Technology Appraisal recommendations in a planned way that supports safe and clinically appropriate practice

[5] *Strategy for UK Life Sciences*, Department for Business Innovation and Skills (http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences)
[6] Department of Health, NHS Improvement & Efficiency Directorate, *Innovation Health and Wealth* Leeds December 2011
[7] Ibid page 7
[8] Ibid page 9

- Establishment of a web portal for innovation with a searchable database of case studies, tools, guides and e-learning to support introduction of a new technology or practice
- Enhancement of the local showcase hospital program to evaluate effectiveness of medical technologies that are safe but don't yet have evidence of effectiveness
- Expansion of the Small Business Research Initiative which provides seed funding to support the development of innovative products and services to meet identified health needs and a commitment by the NHS to procure products which result from SBRI funding.

The report proposes many valuable actions worthy of examination for implementation in Australia. While Australia does not have the benefit of a unified health service this should not act as a barrier to looking at new ways of working with industry to encourage the development of a robust Australian industry.

The UK provides another example of the benefits of closer collaboration between the health system and industry by providing mechanisms to take to market innovations derived from within the healthcare system. Consideration could be given to the establishment of an entity similar to NHS London Innovations (NHSLI) which was established to work with the NHS Trusts in the London area to provide financial returns to the Trusts and while doing so, to address the physical and emotional health of patients and the prosperity of innovation driven economies.

NHSLI identifies potential licensing opportunities for new devices, therapeutics, diagnostics and software developed within the health system. It then fast-tracks to market those innovations that are identified as having commercial potential. It bridges the gap between the NHS, industry, government and public bodies with the aim of making healthcare better through innovation.

Subsidiary businesses have been established for specific purposes such as Xpedite Innovations Management which applies principles of efficient medical innovation and de-risking the product pipeline. It has recently received priming funds from government to provide initial seed and early-stage investment funding for medical start-up companies with a cap of £500,000 per company.

Another business unit is Xcelerate Health Outcomes which provides access to NHS clinical pathways and anonymised patient data to undertake meaningful health economic assessments.

In Canada, the Ontario Government announced the establishment in December 2011 of the MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE). EXCITE is an innovation incubator which brings together a health system (the Ontario Health Technology Advisory Committee), federal government departments, academic hospitals and academic health institutions with industry. It seeks to harmonise health technology evaluation into a single pre-market evidence-based

evaluation for technologies with disruptive potential and specific relevance to health system priorities.

These examples suggest mechanisms that could be explored in Australia for better integrating health and medical research with health system needs and development of the life sciences sector in response.

Another suggestion for supporting more effective translation of health and medical research is the development of innovation hubs which bring together research bodies, hospitals and industry. There are no outstanding examples of an effective hub in Australia although there is under development at Macquarie Park in Sydney a hearing hub based around the Cochlear facility, the leading medical device company for development of the cochlear implant. The physical infrastructure for this cluster is in place. What is missing from this vibrant business and research hub is the social and commercialisation infrastructure to make it internationally competitive. Social infrastructure is the critical component of diffusion of knowledge amongst relevant parties. Commercialisation infrastructure is the mechanism to highlight the potential of research projects at the early stages ensuring the right linkages are in place to get the product to market.

There are several examples of successful medical technology industry clustering in other regions. Medicon Valley[9] spans eastern Denmark and south-western Sweden. It is rated one of the top three life sciences clusters in Europe. The body behind Medicon valley is the Medicon Valley Alliance, a non-profit organization which works to create new research and business opportunities in the region. It also works with its members to improve their innovation skills and competitiveness, and acts as a point of entry for foreign stakeholders.

There are 164 medtech companies in Medicon Valley[10] which, together with 111 biotech and pharmaceutical companies and contract research companies, employ more than 40,000 people. There are 12 universities, five of which offer life sciences degree courses. There are 32 hospitals of which 11 are university hospitals. And there are seven science parks with a focus on life sciences.

Another European life sciences cluster, BioAlps in western Switzerland, claims to be the fastest-growing life sciences cluster in the world. It is the third European centre for research into biotechnology and medical technology after Cambridge and Oxford with more than 750 companies, 500 research laboratories, 20 world-known research institutions, universities and university hospitals, as well as bodies supporting innovation, incubators and venture capital funds.

The universities and higher education institutions in the BioAlps region offer a variety of core facilities dedicated to providing equipment and knowledge necessary

[9] http://www.mva.org/content/us/about_us (accessed 19 January 2012)
[10] http://www.mva.org/content/us/the_region/medicon_valley_statistics (accessed 19 January 2012)

to assist researchers on a fee-for-service basis, ranging from clinical research to assistance with market entry.

In the Asia-Pacific region the best known industry cluster is Singapore's Biopolis. The Singapore Government has supported the expansion of the Biopolis by offering strong intellectual property protection and enforcement, free trade agreements and a competitive tax environment. This support has attracted many multinational medtech companies to establish manufacturing facilities in Singapore, and more recently the manufacturing base has broadened to establish Singapore as a centre for medtech research and development.

In Korea the Daegu-Gyeongbuk High-tech Medical Cluster is an early stage government led project tasked with creating a centre of excellence in medical technology. Daegu is home to five medical universities, 29 general hospitals and 18,000 medical personnel including over 6,000 doctors. There are many incentives for companies to set up premises in the cluster including monthly subsidies for employees, and corporate tax exemptions.

There are emerging corridors and clusters in India and China, for example Gujarat State in India (for pharmaceuticals) and the Beijing Economic-Technological Development Area (BDA), which has facilities such as clean rooms available for use. The governments in these regions recognise the value of clusters in bringing together a group of companies and associated support linked by commonalities and complementarities. These can extend to sharing of infrastructure, business and intellectual property advice. They also nurture SMEs which are an essential feature of an effective cluster.

MTAA notes that the Australian government has announced it will make available through the Australian Research Council, funding for up to 20 hubs as part of an industrial transformation research program. The program will[11]:

- Focus on research areas that are vital for Australia's future economic prosperity—such as engineering, materials science and nanotechnology, communications, chemical engineering and biotechnology
- Support Industrial PhD students and researchers to gain 'hands-on', practical skills and experience in these important areas
- Foster important partnerships between business and universities.

MTAA strongly supports the creation of opportunities which improve linkages, and potentially facilitate improved industry clustering, among research bodies and industry. There is strong evidence to show that effective clustering can engender significant development of entrepreneurial activity.

[11] http://www.arc.gov.au/ncgp/itrp/itrp_default.htm (accessed 19 January 2012)