

# Future directions for health technology uptake, diffusion and disinvestment in Victorian public health services

Department of Human Services workshop discussion paper  
Prepared for 21 March 2007



# Future directions for health technology uptake, diffusion and disinvestment in Victorian public health services

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## Purpose of this document

This document has been produced to provide context, background, analyses and directions for discussion at a workshop on improving the uptake and diffusion of new health technologies and clinical practices and the disinvestment of health interventions that offer no or low health gain.

It is assumed that participants will have read this document and be prepared to discuss the issues, identify gaps and opportunities not addressed and suggest possible ways forward in this climate of rapid technology development, clinician and consumer demand and capped health budgets.

The workshop's output will be an agreed set of recommendations and a description of the work needed to implement them.

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## Foreword

The Department of Human Services (DHS) and the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) welcome you to this workshop. We thank you for your participation and look forward to your contributions to the discussion and planning of future action.

Sustained introduction, diffusion and disinvestment of health technology and clinical practice in the public health sector are difficult. It is a challenge faced by health services and the DHS, and a combined approach is needed to consider these. This discussion paper has been prepared to elicit discussion and recommendation of actions to guide the uptake and diffusion of 'new', and disinvestment of 'old', health technology and clinical practice.

While 'new' health technology can lead to improved patient outcomes, it faces a number of challenges (eg. dissemination of information, assessment of clinical and cost effectiveness, access to trained workforce, appropriate diffusion across the sector, cost). In addition, some 'old' health technology may have been good once, but maybe is not appropriate now in the light of accumulating evidence and experience.

This paper is not a DHS policy document, but rather an attempt to summarise existing policy, processes and key influences that impact on Victorian public health service uptake, diffusion and disinvestment of health technology and clinical practice.

I thank DHS staff and members of VPACT and those of you who have already contributed by virtue of participating in the current process to introduce new technology and clinical practice, to the development of this discussion paper and to the planning for the day. And I thank you for taking the time and effort in joining us for this workshop.

I expect that the workshop will lead to recommendations and strategies that will require time and commitment from some of you. However, given the rapid developments in technology and clinical practice, their potential impact on improving health care, I believe that now is the time to address these issues and develop locally-relevant strategies that support the appropriate uptake, diffusion and disinvestment of health technology and clinical practice to improve health outcomes for all Victorians.

Thank you again for your participation.



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## Abbreviations

ACAES	Advisory Committee on Access to Elective Surgery
AHMAC	Australian Health Ministers' Advisory Committee
ARTG	Australian Register of Therapeutic Goods
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures–Surgical
BMS	bare metal stent
CAG	Clinical Advisory Groups
CPAP	Chemotherapy Pharmaceutical Access Program
DES	drug-eluting stent
DHS	Department of Human Services
DTC	Drugs and Therapeutic Committees
HealthPACT	Health Policy Advisory Committee on Technology
HTA	Healthy technology assessment
ICS	Integrated Cancer Service
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NFC	Nationally Funded Centres
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NTCP	new technology and clinical practice
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Schedule
PDC	Prostheses and Devices Committee
PoCE	Panel of Clinical Experts
QUM	quality use of medicines
TGA	Therapeutic Goods Administration
VMAC	Victorian Medicines Advisory Committee
VPACT	Victorian Policy Advisory Committee on Clinical Practice and Technology
WIES	weighted inlier equivalent separations

## Introduction

*So much is expected, by the public and by politicians. So much is possible. But resources are finite and choices have to be made about where and how to invest – and disinvest – to make the most out of the nation's funding for health (NICE 2006).*

Health technology, in the context of this discussion paper and the forthcoming workshop, include the following technologies and clinical practices: prostheses, implantable devices, diagnostic tests, medical and surgical procedures and high cost pharmaceuticals. It does not include capital equipment (eg. CT, MRI), capital works or information technology.

Advancing developments in new health technology are major drivers in the growth of health care expenditure. Such developments are usually welcomed by patients, payers and providers, and beneficial results can include enhanced patient outcomes, improved quality of life and reduced length of stay and procedural costs. Conversely, such developments can increase procedural costs and diffuse rapidly into the health sector with limited consideration of supporting evidence and impact on the health sector.

Industry and health sector reports indicate that the increasing cost of health technology accounts for approximately two per cent of the annual growth in real health care expenditure (KPMG 2001, Wanless 2002, Access Economics 2003, Australian Government 2003, Paxton Partners 2003). While providers are keen to introduce new health technology, it is often not clear how they, and indeed the government, will incorporate costs for these into the usual funding mechanisms in the face of the overall growth in health care expenditure.

There is often no process, nor incentive, to ensure that the use of health technology take into consideration the following factors that many consider should underpin provision of care beneficial to the patient and sustainable in a health system:

- Evidence of safety, clinical effectiveness and cost effectiveness
- Evidence of appropriate implementation throughout the health sector
- Monitoring of use and outcomes
- Continued evaluation to inform ongoing use and funding.

Implementing and evaluating appropriate, safe and effective new technology and clinical practice within a systematic framework will inform its ongoing use and funding in the public sector. Similar processes and frameworks should also inform disinvesting health interventions that offer no or low health gain for these processes may provide an opportunity to invest in alternative proven and cost effective health interventions. Disinvestment of health interventions is a policy challenge that requires greater attention, both for quality of care and sustainable resource allocation. Some health services are already undertaking some of these activities, and this provides an opportunity for spreading reform across the system.

The Department of Human Services (DHS) and the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) have convened this workshop to facilitate a constructive and strategic discussion to inform policy formulation and development of implementable strategies to enhance the appropriate uptake and diffusion of new technology and clinical practice and to disinvest health interventions that offer no or low health gain. It will support dialogue between clinicians, health service managers, policy makers and consumer representatives.

This document has been prepared to provide workshop participants with:

- A vision of where we want to be
- An overview of the current environment and issues surrounding the uptake and diffusion of new technology and clinical practice in Victoria's public hospitals
- Issues around disinvesting health interventions with little or no health gain.

This document is not a statement of DHS policy and is presented solely to facilitate discussion among workshop participants.

## Principles guiding health technology uptake, diffusion and disinvestment

This set of principles provides the basis for moving forward to develop and implement

- A long-term (five year) framework supports the appropriate uptake, diffusion disinvestment of health technology across Victoria's public hospitals.
- Transparent and robust processes are developed and implemented to support the framework.
- Funding mechanisms are established to support the implementation of the framework and the ongoing funding of appropriate health technology.
- Information about new and emerging technology and clinical practice is communicated between stakeholders.
- Introduction and diffusion of new technology and clinical practice is aligned with departmental and health service priorities.
- Introduction and diffusion of new technology and clinical practice is evaluated to inform its ongoing use and appropriate funding.
- A robust methodology/criteria for decision making informs the appropriate introduction and diffusion of new, and disinvestment of 'old', health technology.
- A prioritisation system considers the needs of patients and providers, the statewide impact of implementation, financial and workforce capacity requirements and the priorities of health service and the department.
- Clinical and academic expertise is engaged to undertake evidence assessment and to inform recommendations and decisions.
- Mechanisms are established, which are informed by appropriate evaluation, to support mainstreaming of funded new technology and clinical practice.
- Disinvesting health interventions that offer no or low health gain leads to improved patient management, better/targeted resource allocation and reinvestment of any savings into additional uptake of new technology and clinical practice.

## The current environment

New health technologies offer opportunities to raise the quality of diagnosis and treatment and to increase the number of people who may benefit from health care. The paradox is that while new technology items themselves may be cost saving, the overall process of introducing new technology into the system is driving an increase in health care expenditure. Inconsequently, in an environment of limited health funding, the introduction of new health technology must compete with established budgets, practices, policy and often mindsets, and demonstrate a benefit in health outcomes.

DHS is the first jurisdictional health department in Australia to have developed a program for introducing new technology and clinical practice across the acute public health sector *and* allocating funding to support the implementation of these initiatives.

This innovative and evidence-based program has encouraged the uptake and statewide diffusion of new technology and clinical practice in the face of a range of clinical and cost pressures. These include a desire to provide the best treatment, to be the first to provide the best treatment, to provide the same type of care provided in the private health sector, to improve health outcomes associated with current standards of care and to reduce hospital length of stay. Some of these are considered in detail below.

Over the last 12 months, other jurisdictions and area health services have established similar programs that are based on the Victorian model. It is not clear whether these programs have been allocated budgets to support the implementation of new technology and clinical practice.

The Victorian experience has seen success in encouraging uptake of new technology and clinical practice. The pressure now is at the next stage of development, i.e. sustaining this approach in an era when advances in medical technology are already a major driver of the growth in real health care expenditure (see below).

If Victoria wants this program to be sustainable and to be seen as leading the uptake and diffusion of new technology and clinical practice, consideration needs to be given to developing a long-term framework that considers:

- Proactive interactions between health services
- Developing and strengthening mechanisms to better support health services in their utilisation of new technology and clinical practice
- Providing incentives to reduce practices that offer little or no health gain.

These are not easy tasks to undertake in an environment where health technology is perceived to bring large gains in health, sometimes with limited supporting evidence.

## Introduction of new health technology in Australia and Victoria

At the federal level, the Commonwealth Government recently commissioned work through the Department of Treasurer and the Productivity Commission, respectively, to consider the impact of regulatory burdens on business and advances in medical technology in Australia. Australia also has internationally recognised, and widely envied, regulatory mechanisms that consider availability and reimbursement of health provision and interventions.

At the state level, programs and systems have been established to provide mechanisms to guide the safe and appropriate introduction of new health technology in Victoria's public hospital sector.

### Work informing introduction of new health technology

#### Productivity Commission

In August 2005, the Productivity Commission released its research report *Impacts of advances in medical technology in Australia*, which detailed and explained the impact of advances in medical technology on public and private healthcare expenditure, and the associated costs and benefits for the Australian community. This report identified that advances in medical technology have been a major driver of the growth in real health care expenditure and estimated that the cost of technological change contributed 1.9 per cent to the annual growth in real health care expenditure of 5.3 per cent, or 36 per cent of the annual growth in real health care expenditure from 1992-93 to 2002-03.

The DHS submission to this report noted:

- Any gains from cost reductions associated with new technology tend to be put into providing additional treatments
- Higher input costs are also increasing hospital expenditure as:
  - Additional parts or drugs are added to existing procedures, driving up costs
  - Safer, more advanced and more expensive technology replaces less costly technology
  - Developments in pharmaceuticals can be very costly and are generally more expensive than older, more established, pharmaceuticals.

The key points identified by the Productivity Commission were:

- Advances in medical technology have brought large benefits but have also been a major driver of increased health spending in recent years. In many cases, increased expenditure on new medical technologies reflects improved treatment and a significant increase in the number of people treated.
- Overall, advances in medical technology arguably have provided value for money – particularly as people highly value improvements in the quality and length of life – but the cost effectiveness of individual technologies in practice varies widely and for some is simply unknown.
- Variations in cost effectiveness, and relatively low use by some demographic groups, suggest scope for expanding use of some technologies and possibly reducing use of others to increase net community benefits.
- Better coordinated, more systematic health technology assessment (HTA) with transparent objectives, underpinned by the principle of enhancing overall community wellbeing, would be a good step forward. HTA can help to target use of new technologies and promote overall cost effectiveness of healthcare spending.

- Evidence and needs based access to new technologies is preferable to existing, often blunt, rationing mechanisms.
- Systematic reviews of efficacy and cost effectiveness of new technologies once they are in use could promote overall cost effectiveness of healthcare, without unduly delaying their introduction.
- Greater procedural transparency and community involvement in HTA have the potential to foster greater acceptance of technology funding decisions and to help ensure that HTA is not used simply to restrain expenditure.
- The next decade or so could see the emergence of revolutionary technological advances based largely on knowledge of the human genome. Many are expected to provide significant benefits to the Australian community, but at significant cost.
- Such technological advances, interacting with (and encouraged by) increasing demand for health services driven by income growth, accelerating population ageing, community expectations that new technologies will be accessible to all, the commitment of doctors to offer the best-available treatments, and subsidised consumer prices, will make for a potent mix, placing increasing pressures on the private and public health systems.
- These pressures underscore the need for better information about the costs and benefits of technology. But technology is only one input in healthcare. Problems related to technology use often reflect broader structural, incentive and resourcing issues in the health system.
- There is a pressing need to explore what the community considers is an appropriate level of subsidised access to healthcare and the technology it embodies, and the institutional and incentive structures that will deliver it efficiently and equitably.

*Impacts of advances in medical technology in Australia* is a research report, which only provides findings (i.e. there are no recommendations or expectations). The purpose of a Productivity Commission research report is to inform the field.

### **Taskforce on reducing regulatory burdens on business**

In October 2005 the Prime Minister and the Treasurer announced the appointment of a Taskforce to identify practical options for alleviating the compliance burden on business from Government regulation. The Taskforce was chaired by Mr Gary Banks, Chairman of the Productivity Commission, and included business and small business representation.

The Taskforce delivered its report *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business (Report)* to the Government in January 2006.

The *Report*, guided by the views of stakeholders representing industry, small business, consumers and Australian Government, made 178 recommendations on actions to reduce red tape across a wide range of policy areas. The Report also made recommendations on actions to improve regulation making processes and regulatory gate keeping.

The Report considered a range of issues, including health and health-related regulation. Recommendations were made regarding general medical practice, private health insurance, pharmacy, therapeutic products and medical devices and aged care. The six recommendations relating to therapeutic products and medical devices, including the Commonwealth Government's response to these, are summarised at Appendix 1.

One of the recommendations is that ‘The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.’

The Australian Government has agreed to a review of Health Technology Assessment (HTA) in response to this recommendation. The Review will consider the processes of the Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC) to identify opportunities for enhancing the efficiency and transparency of current systems for regulation and approval of medical procedures and devices.

The draft terms of reference are currently being developed by the Department of Health and Ageing. It is expected that the terms of reference and process for the Review will be finalised in the near future. The Review will include opportunities for stakeholder consultation.

## National systems informing introduction of new health technology

### Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC makes recommendations to the commonwealth Minister for Health and Ageing about which drugs and medicinal preparations should be available as pharmaceutical benefits, and to advise the Minister about any other matter relating to the Pharmaceutical Benefits Scheme (PBS) that is referred to it by the Minister. The range of drugs and formulations available under the PBS provides a formulary of drugs to meet the health needs of the majority of the Australian community.

The PBAC considers the effectiveness, cost-effectiveness and clinical place of a product compared with other products already listed in the PBS for the same, or similar, indications. Where there is no listed alternative, the PBAC considers the effectiveness, cost-effectiveness and clinical place of the product compared with standard medical care or the benefits for patients the new product will provide compared to the cost of achieving those benefits. When recommending listings, the PBAC also provides advice regarding comparison with alternatives or their cost-effectiveness ('value for money').

Further information about the PBAC is at [www.health.gov.au](http://www.health.gov.au).

### Medical Services Advisory Committee (MSAC)

Established in 1998, the principal role of MSAC is to provide evidence-based advice to the Australian Government on new medical technologies and procedures in terms of their safety, effectiveness and cost effectiveness. This advice informs Australian Government decisions about public funding (i.e. through the MBS) for new, and in some cases existing, medical procedures. MSAC has the capacity to assemble and review available evidence. In some circumstances, MSAC can recommend interim funding to enable data collection, within an agreed research framework, in order to establish the evidence base.

The MSAC terms of reference are to:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness and under what circumstances public funding should be supported
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

Further information about MSAC is at [www.msac.gov.au/](http://www.msac.gov.au/).

## Prostheses and Devices Committee (PDC)

The PDC is a ministerially appointed non-statutory committee established to make recommendations to the Minister for Health and Ageing about the listing and benefit amounts of new and existing prostheses and devices health insurance funds are required to fund for their members. PDC recommendations are based on advice from the Clinical Advisory Groups (CAG) and the Panel of Clinical Experts (PoCE).

The PDC recommendations are primarily about the clinical effectiveness and relative clinical effectiveness of products. The PDC recommendations on benefit levels are informed by advice from benefit negotiators for products recommended for listing on the Prostheses List.

The PDC's terms of reference are to:

- Make recommendations to the Minister on appropriate listing and benefit amounts of medical devices meet the criteria for listing on the prostheses list
- In making the recommendations, consider the recommendations, comments and/or advice provided by its CAGs, PoCE, the Prostheses and Devices Negotiation Group and sponsors of prostheses
- Consider and recommend the listing of new items within agreed timeframes
- Advise the Department of possible concerns relating to the use of prostheses such as MBS items.

The Committee's recommendations are based on the:

- Clinical effectiveness provided by each product, taking into consideration existing clinical practice or where available, clinical guidelines developed by craft groups
- Benefit amount negotiated by the PDNG.

Further information about the PDC is at [www.health.gov.au](http://www.health.gov.au).

## Nationally Funded Centres

The Nationally Funded Centres (NFC) Program is a national policy for public sector provision of high cost, highly specialised clinical practices and technologies with limited demand. The Australian Health Minister's Advisory Council (AHMAC) oversees the NFC Program and associated policy.

The objectives of the NFC Program are to ensure that:

- There is maximal access to certain high cost, low demand, new and emerging technologies regardless of geographical location, in the context of workforce and resource availability
- These technologies are provided efficiently and effectively
- Requirements for high quality and safe introduction and ongoing provision of these technologies have been defined and implemented
- Health and cost outcomes of these technologies are monitored and evaluated.

For a technology to be considered for provision in an NFC Program, it must be an established clinical practice requiring a national population base for efficient and effective service provision. The scope of technology eligible for consideration as a NFC includes devices, prostheses, techniques, skills or expertise (or personnel with particular skills or expertise) and/or procedures, or combinations of these.

High cost low demand pharmaceuticals are not eligible to be considered for a NFC program unless they are a component of care in the provision of a particular practice or technology. Service delivery of technologies approved as NFC Programs may occur in one or more sites and is restricted to these sites.

Provision of some technologies in NFCs will be long term. With others, the duration will be shorter as the practice becomes diffused across the health system. In some instances, approval to provide a technology in a NFC may be withdrawn due to evidence not available at the time of its approval. Funding for NFCs is provided by state and territory jurisdictions according to a weighted population based formula based on an agreed price for each procedure.

An NFC Reference Group is responsible for managing the NFC Program, for ensuring submissions for new NFCs are assessed (subsequent to approval by AHMAC) and that existing NFCs are reviewed regularly. The NFC Reference Group also determines the annual budgets for NFCs. The NFC Reference Group includes representatives from the Australian Government and each jurisdiction.

MSAC currently undertakes reviews and assessments for proposed NFCs as required. It has reviewed the experience and performance to date of the following established NFCs and makes recommendations to AHMAC regarding their future operation:

- Pancreas Transplantation Program, Westmead Hospital, Sydney
- Pancreas Transplantation Program, Monash Medical Centre, Melbourne
- Paediatric Liver Transplantation Program, Royal Children's Hospital (RCH), Melbourne
- Paediatric Liver Transplantation Program, RCH, Brisbane
- Paediatric Liver Transplantation Program, Royal Prince Alfred Hospital, Sydney
- Paediatric Cardiac Transplantation Program, RCH, Melbourne

MSAC recently assessed the suitability of Pulmonary Thromboendarterectomy, Peritonectomy and Selective Dorsal Rhizotomy for their establishment as new NFC Programs. AHMAC will consider endorsing these at its March 2007 meeting.

Further information about NFCs is at [www.health.vic.gov.au/newtech/nfc.htm](http://www.health.vic.gov.au/newtech/nfc.htm).

### **Health Policy Advisory Committee on Technology (HealthPACT)**

Introducing new technology into a health system without warning or in an uncontrolled manner can have a wide-ranging impact on the health care system, including ballooning costs, a lack of preparedness by training and accreditation organisations and consequent patient safety concerns. Horizon scanning provides 'early warning' to policy makers of particular technologies that are emerging and may have a significant impact on the health system within the next 3-5 years. With this information, policy makers can put in place mechanisms to control and/or streamline the introduction of the new technology.

MSAC established a horizon scanning program in late 2003. Its aim is to identify and share information on 'big ticket' emerging health technologies before they are widely diffused so their introduction can be better managed. The activity complements but precedes health technology assessment, which MSAC oversees.

The horizon scanning program is conducted in collaboration with the Health Policy Advisory Committee on Technology (HealthPACT). HealthPACT comprises representatives from all State and Territory Governments as well as the Australian Government and the New Zealand Ministry of Health.

The Department of Health and Ageing contracts the University of Adelaide's *Adelaide Health Technology and Assessment* and the *Royal Australasian College Of Surgeons' Australian Safety and Efficacy Register of New Interventional Procedures – Surgical* (ASERNIP-S) to support the horizon scanning program.

These agencies identify emerging technologies and scan the literature to develop summaries, of which almost 200 have been developed. They provide a snapshot of information about what is known about the technology, the stage of its development, clinical need and its likely impact on the health system. During the same period more than 20 horizon scanning reports were also developed.

HealthPACT considers the information contained within the summaries produced and makes a decision to:

- archive the report
- monitor any further diffusion or development of the technology in six or twelve months
- have a more comprehensive horizon scanning report prepared on the technology, or
- refer the technology to the MSAC for a full health technology assessment.

In 2005 the horizon scanning website [www.horizonscanning.gov.au](http://www.horizonscanning.gov.au) was launched. The site contains copies of all summaries and horizon scanning reports, as well as more general information on horizon scanning in Australia. MSAC is also an active participant in the European Information Network on New and Changing Health Technologies (EuroScan), which is a collaborative network of agencies involved in the evaluation of new and changing technologies.

It is proposed that the department will disseminate information generated by HealthPACT to health services through their Technology/Clinical Practice Committees (see later), and vice versa. It is anticipated this sharing of information may better inform health service consideration and collaboration in preparing and making submissions to the Victorian Policy Advisory Committee on Clinical Practice and Technology regarding the introduction of new technology/clinical practice.

## Local systems informing the introduction of new health technology

### New Technology Program (1997-98 to 2003-04)

Historically in Victoria, each health service has been responsible for deciding what technology or clinical practice is introduced and how it is funded, with no dedicated central process or funding to support its introduction. This has, at times, led to fragmented and unregulated introduction of technology/clinical practice within the Victorian public health sector. Ten years ago DHS developed a program to support and fund the introduction of new technology/clinical practice in public hospitals.

The New Technology Program was established in 1997 with recurrent funding to support the introduction of new technology that would be incorporated into routine clinical practice. As defined previously, a new technology is defined as a prosthesis, implantable device, diagnostic test, pharmaceutical or medical or surgical procedure that had been approved for use by the national regulator, the Therapeutic Goods Administration (TGA), not less than two years previously.

Health services were invited annually to submit requests to the department for review and consideration of funding the introduction of the new technology. To enhance this process, the department developed a proforma outlining the specific information sought from the health services, including items regarding the safety and the clinical and cost-effectiveness of the new technology. An internal decision process informed consideration of health service submissions.

In its first year (1997-98), this program was instrumental in funding the introduction of the following items, all of which are now in routine clinical use:

- Coronary, aortic, arterial, venous, intracranial, oesophageal and ureteric stents
- Implanted cardiovascular defibrillator
- Perioperative transoesophageal echocardiography
- Deep brain stimulation
- Device closure of atrial septal defects.

The following initiatives were subsequently introduced over time to support a robust submission and decision-making process to inform the introduction of new technology into the public arena:

- Additions to the proforma to capture additional clinical and cost information
- Analysis of cost weights to provide funding information regarding the submission
- Consideration of decisions of national agencies (eg. PBAC, MSAC)
- Expertise in health technology identification and assessment.

One of the annual challenges for the department was coping with the volume of submissions seeking funding for new items, which exceeded 300 one year. Many of these were for the same item (sometimes from up to 10 different health services). This impacted on the time to analyse and consider submissions and allocate funding, which often eventuated well into the financial year for which funding was meant to be provided.

### Funding of new technology through the New Technology Program

The table below summarises the variable recurrent funding of the New Technology Program, the amount allocated each year to fund items on a recurrent basis and the proportion of budget allocated to items funded by the Program in previous years.

Year	Annual program budget \$ million	Budget allocated to previously funded items		New technology items
		\$ million	% of annual budget	
1997-98	\$10	\$0	0%	Mostly stents & ICD, TOE, DBS, ASD
1998-99	\$10	\$5.8	58%	Combination of devices and drugs
1999-2000	\$10	\$6.9	69%	Combination of devices and drugs
2000-01	\$13.5	\$6.75	50%	Combination of devices and drugs
2001-02	\$13.5	\$5.94	44%	Most new items were drugs
2002-03	\$13.5	\$6.89	51%	Most new items were drugs
2003-04	\$13.9	\$10.8	78%	Only new item was DES

The resultant call for submissions after the financial year had commenced often meant that funding was not allocated until some months into the financial year. This limited the opportunity for health services to adequately implement the new technology/clinical practice or reach its estimated - and funded - activity by 30 June. In addition, the funding allocated was cash flowed as a lump sum. There was no requirement or system to monitor or report to DHS on the use of the funding new technology/clinical practice.

A good number of applicants complained they received no funding for the new technology/clinical practice, particularly after being notified by DHS of the funding allocated for a defined number of procedures/patients. This resulted in some clinical departments in some health services running up a debt that often impacted on their ability to meet their estimated activity. Informal feedback indicates that health services did receive the funding allocated, but this was reallocated internally for other purposes, often without advising the relevant clinical department that had already commenced utilising the new technology/clinical practice.

### Mainstreaming of items after New Technology Program funding

The intent of the program was to fund new technology for a period of two years, after which time costs would be mainstreamed (i.e. incorporated into usual funding mechanisms in an ongoing, recurrent, manner).

Mainstreaming costs for items funded through this program were proposed to occur through one or more of the following funding mechanisms:

Funding responsibility	Proposed funding mechanism
State (i.e. DHS)	Casemix: <ul style="list-style-type: none"> <li>• Payment for inpatient services through usual hospital payments (WIES)</li> <li>• Payment for outpatient services through the Victorian Ambulatory Classification and Funding System (VACS)</li> </ul> Specified grants (payments for specified purposes)
Jurisdictions (i.e. all States and Territories)	Nationally Funded Centres (NFCs)
Commonwealth	Medicare Benefits Schedule (MBS) Pharmaceutical Benefits Schedule (PBS) Chemotherapy Pharmaceutical Access Program (CPAP)

Generally, items funded through the New Technology Program can more quickly be incorporated into casemix funding as this is a local system. However, a major issue regarding mainstreaming costs through other mechanisms (eg. PBS and MBS) is that often there is limited evidence of clinical or cost effectiveness to support reimbursement, upon which funding is often based, indicating there are differences in requirements for evidence to support funding through different funding mechanisms. In fact, the New Technology Program can be seen as a disincentive for listing pharmaceuticals and devices on the PBS and Prostheses List, respectively, as it takes the pressure off industry to seek listing of these products.

In reality, there has been limited opportunity to mainstream costs for new technology due to the range of different funding mechanisms and their requirements, limited capacity to absorb costs for new technology and, in some cases, limited processes for capturing the costs of new technology and ensuring equitable distribution of funds. This has resulted in the Program funding items beyond two years (eg. prostacyclin for paediatric pulmonary hypertension), which reduced the budget for, and limited, introduction of new items.

In summary, for the years 1998-2004, the challenges impacted upon providing equitable access to new technology or their ongoing funding were:

- uncertainty around the annual budget for new technology
- lack of collaboration between health services seeking funding for the same technology
- large numbers of submissions (often more than 200 requests) for funding new technology each year

- allocation of a significant portion of the Program budget to items for more than the intended two years
- inadequate processes for mainstreaming costs of new technology outside of current cost weight studies.

### **New Technology/Clinical Practice (NTCP) Program (2004-05 to present)**

In 2004-05 DHS developed a process to enable a more systematic approach to fund and coordinate the introduction of new technology and clinical practice in public health services across Victoria (i.e. on a statewide basis). This included the commencement of an external committee, the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) and a revised submission process. The definition of new technology and clinical practice was revised to describe a technology/clinical practice that had not been introduced into the Victorian public health sector within the previous two years. All other criteria, including TGA approval where appropriate, are as indicated.

### **Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT)**

The role of VPACT is to advise the department and make recommendations on issues including:

- Mechanisms for early identification of new technology/clinical practices
- Assessment of clinical and cost effectiveness of existing and new technology/clinical practice
- Establishment of Nationally Funded Centre applications
- Priorities for the introduction and use of new technology/clinical practice
- Policies and procedures for introducing new technology/clinical practice in public health services
- Policies about health service delivery following introduction of New Technology/Clinical Practice
- Requirements for evaluating and monitoring the introduction and use of new technology/clinical practice
- Disseminating information about new technology/clinical practice.

VPACT members have academic, clinical, health service and consumer-related knowledge and expertise, including quality and safety, health policy, health service delivery, health technology assessment, health economics and clinical pharmacology.

The activities of VPACT complement and supplement those being undertaken by MSAC, PBAC and HealthPACT. It addresses Victorian specific issues and utilises information from these agencies where available. From time to time, VPACT sponsor work on behalf of the department and HealthPACT. VPACT can also consider good practice management of medical and surgical supplies regarding the use of new or existing technologies or clinical practices.

The VPACT Terms of Reference is at Appendix 2.

Further information about VPACT is at [www.health.vic.gov.au/newtech/committee.htm](http://www.health.vic.gov.au/newtech/committee.htm).

### **Funding of the NTCP Program**

Since 2004-05, the New Technology/Clinical Practice Program annual recurrent budget has remained at \$9 million. The department confirmation that this will be the Program's annual recurrent budget ongoing has supported an earlier call for submissions than had been undertaken previously. It is planned for February to remain as the submission deadline, which will support health services plan future submissions.

### **Revised submission process**

A revised proforma seeks information on clinical need, feasibility, safety, clinical and cost effectiveness, governance and financial impact. Where more than one health service wants to introduce the same new technology/clinical practice, all must collaborate to prepare a single joint submission. Submissions are short-listed against inclusion and exclusion criteria. Departmental officers short-list all submissions for VPACT consideration, and VPACT subsequently endorses these.

Short-listed submissions are reviewed in depth by VPACT, which makes a recommendation to accept, reject or defer. After endorsing a VPACT recommendation, the department consults with health services to agree on funding, monitoring and reporting requirements. VPACT also considers reasons for not short-listing submissions.

Each submission round raises ambiguities and queries as a result of differing interpretations of the information requested through the proforma. The proforma is modified annually to address these issues.

### **Results to date**

The revised New Technology/Clinical Practice Program has resulted in fewer submissions, more joint submissions and fewer funded submissions:

- For 2005-06: 26 submissions, 9 short-listed and 4 funded
- For 2006-07: 12 submissions, 6 short-listed and 4 funded
- For 2007-08: 14 submissions, 9 short-listed.

Recent submissions are also of a higher quality and, importantly, detail a plan for implementing the proposed new technology/clinical practice.

This process has allowed for implementation of new technology/clinical practice on a truly statewide basis with specified monitoring and reporting requirements from the field, which informs consideration about mainstreaming costs in subsequent years.

New technology/clinical practice recommended by VPACT for introduction into the Victorian public health sector since 2004-05 are summarised opposite.

Year	New Technology/Clinical Practice items introduced	Budget allocated	
		\$ (million)	% of annual budget
2005-06	<ul style="list-style-type: none"> <li>• Paediatric lung transplantation</li> <li>• Foetal laser photocoagulation therapy for twin:twin transfusion syndrome</li> <li>• Prostacyclin as a bridge to lung transplantation</li> <li>• Selective dorsal rhizotomy for children with complex cerebral palsy</li> </ul>	\$2.1	23%
2006-07	<ul style="list-style-type: none"> <li>• Percutaneous sclerotherapy for paediatric peripheral arteriovenous malformations</li> <li>• Small bowel transplantation for intestinal failure</li> <li>• Double-balloon enteroscopy for obscure bowel syndromes</li> <li>• Ultrasound-guided regional anaesthesia to improve local anaesthesia</li> <li>• Cardiac MRI to diagnose cardiac pathology</li> <li>• Foetal MRI to diagnose foetal congenital abnormalities</li> </ul>	\$4.4	49%

### What's been achieved through the New Technology/Clinical Practice Program

This is the first time policy and process has been implemented in Australia to ensure a systematic approach to the introduction, and funding, of new technology/clinical practice in the public health sector. This approach has resulted in benefits for consumers, payers and providers, including:

- Dedicated recurrent funding to support introduction of new technology and clinical practice
- Strengthening relationships between the department and health services, and between health services
- Streamlined budgeting and submission process, resulting in more timely decisions
- Establishment of VPACT, which:
  - Has engaged experts with relevant clinical and technical expertise
  - Mirrors national processes (i.e. MSAC, PBAC, HealthPACT)
  - Legitimizes authority for its decisions
  - Has enabled development of guidance for health services to establish committees to consider the local introduction of new technology and clinical practice, which aligns with departmental policy
- Health service understanding of the issues related to introducing new technology
- Victoria is represented on HealthPACT, a national forum, that contributes to agenda setting regarding the identification and evaluation of new and emerging technologies and clinical practices that have the potential to impact on the health system over the next 3-5 years
- Government providing leadership for public health sector innovation.

## Guidance for Victorian public health services to establish Technology/Clinical Practice Committees

Several health services identified a need several years ago to establish a local committee to consider and oversee the introduction of new technology/clinical practice at the local level. These committees developed criteria and guidance to advise and assist clinicians introduce NTCP. However, most health services had not established such committees, which often resulted in ad hoc, fragmented and non-equitable introduction of new technology/clinical practice across the public health sector.

The department identified this as an opportunity to assist health services establish a process to better coordinate the introduction of new technology/clinical practice within the health service. Oversighted by VPACT, the department developed draft guidance for metropolitan and regional health services to establish local Technology/Clinical Practice Committees. The draft guidance was informed by processes established and guidance developed elsewhere, including those health services with existing committees, the Royal Australasian College of Surgeons and NSW Health. The draft guidance is currently being updated following feedback from health services and other areas of the department.

The local committee's role is to oversee the local introduction of new technology/clinical practice, to submit regular reports to VPACT about new technology/clinical practice implementation in their health service and to endorse VPACT submissions from health services to ensure alignment with health service priorities. These committees are currently being established.

Further information about this guidance is at [www.health.vic.gov.au/newtech](http://www.health.vic.gov.au/newtech).

## Victorian Medicines Advisory Committee (VMAC)

VMAC, an expert group established in 2005, advises the department and leads the strategic direction and policy development for Quality Use of Medicines (QUM) in Victoria. In particular, VMAC leads the application of the National Medicines Policy and the National Strategy for QUM in Victorian hospitals and at the primary care interface.

The following strategies will be used to achieve this aim:

- Promoting the implementation of best evidence based practice in QUM through multidisciplinary collaboration with QUM partners, locally, statewide and nationally.
- Developing an effective communication strategy for sharing information about QUM, within Victoria and with interstate partners.
- Promoting a culture supporting QUM within healthcare organisations.
- Advising on education and training that supports best practice in QUM.
- Advising on research and development in QUM to support best evidence based practice.
- Evaluating QUM activity within Victoria through examination of performance indicator reports for medication safety and other aggregated data and advise on any strategies and interventions to address issues identified.

VMAC will play an important role in ensuring the safe, appropriate and cost-effective use of medications in Victorian hospitals and the wider community. Positioned at the hub of an extensive network, VMAC will identify QUM issues, facilitate independent and expert evaluation of these issues and ensure appropriate and rapid dissemination of information to those who need it.

VMAC and VPACT have commenced working closely where VPACT has recommended introducing a high cost pharmaceutical into the public sector.

Further information about VMAC is at [www.health.vic.gov.au/vmac](http://www.health.vic.gov.au/vmac).

### **Access to health technology assessment expertise**

Australia is internationally regarded as a pioneer and leader in the evidence-based processes for assessing new technologies and clinical practices to gauge their safety, efficacy, clinical effectiveness and cost effectiveness in order to determine their eligibility for public reimbursement and, theoretically, universal access.

Internationally, it is often the norm for an academic agency to provide evidence to policy-makers to inform policy consideration. Nationally, MSAC and PBAC commission agencies to provide evidence-based assessments to inform consideration for MBS and PBS listing, respectively.

Several agencies exist in Victoria with this expertise but are not formally engaged to provide support to inform policy or decisions in the public health sector. VPACT can commission evidence reviews to inform policy and practice consideration, however, this is not currently undertaken within a strategic framework.

## The future

### Funding of high cost chemotherapy drugs

The department is considering the VPACT process as the basis for a high cost chemotherapy drug program. The establishment of a separate program for these drugs is driven by a number of considerations:

- A significant proportion of all new high cost drugs are chemotherapeutics.
- Decisions by hospitals to utilise new drugs, undertaken in an ad hoc manner by hospital Drug and Therapeutic Committees (DTCs), can be influenced by local factors such as overall financial performance of the hospital, leading to local and statewide inequalities in public availability of these drugs.
- DTCs may not have the expertise or resources to undertake or commission a cost effectiveness analysis of a drug prior to using it in the hospital.
- In the absence of independent and authoritative review of these drugs, information available to local decision makers may come largely from manufacturers or from overseas agencies. This information may be biased or lack relevance in the Australian setting. One impact of this can be uptake-by-stealth of these agents, with flow on effects to hospital budgets.

Possible benefits of this approach could include:

- Review by an independent committee with broad expertise and statewide authority that would overcome ad hoc approaches to high cost chemotherapy drug delivery
- Support of rational decision making regarding utilisation of these agents
- Provide clarity for clinicians and the public over the costs and benefits of particular new (high cost) chemotherapy drugs

Other considerations regarding this approach need to address integration with existing and appropriate policy and programs, risks and expectations, such as:

- Submissions made, or at least endorsed, by individual/all Integrated Cancer Services (ICS)
- Creating high community and clinical expectations over availability of high cost chemotherapy drugs
- Strategies to mitigate risks and inform potential ongoing funding mechanisms for new chemotherapy drugs.

## Systematic implementation of new technology

While DHS processes have been developed for funding and coordinating the statewide introduction of new technology/clinical practice, these could be enhanced to better support appropriate and more systematic introduction of new technology by working more closely with health services and utilising outputs from existing national and state agencies.

Such improvements are considered to include:

- Improving communication between health service
- Defining a system and developing processes that underpin evidence-based consideration, and coordinated implementation, of new technology/clinical practice on a statewide basis
  - Aiding health service understanding and navigation of the system
  - Ensuring introduction of new technology and clinical practice aligns with health service strategic goals
  - Coordination and collaboration of health services in preparing joint New Technology/Clinical Practice Program submissions that align with health service objectives and priorities
- The system and processes are effectively informed by, and link with, existing national systems
- Continued alignment of the New Technology/Clinical Practice Program with existing DHS policy
- Ensuring that evidence continues to inform policy and decision making
- Ensuring mainstreaming of new technology and clinical practice through the most appropriate funding mechanism
- Better planning due to the range of local and national funding mechanisms that have different requirements and processes
- Evaluating the effectiveness of new technology and clinical practice to inform ongoing funding and clinical care
- Decisions informed by future demand, statewide and health service capacity and clinical leadership to support volume/quality issues
- Ensuring a sufficient budget to support introducing appropriate new technology/clinical practice, including high cost pharmaceuticals.

Is investment required? New technologies will continue to utilise an increasing proportion of the health care budget, particularly as newer drugs and devices for expanded clinical indications become available. Improved mechanisms to introduce and monitor new technologies will require additional funding, but will also result in a more systematic approach and improved access to proven technologies.

## Disinvesting technology and clinical practice

Historically, some health care interventions have diffused throughout the health sector and those of limited clinical effectiveness and cost-effectiveness may still be in practice. Disinvesting health interventions that offer no or low health gain (eg. are unproven, outdated or cost ineffective) provides an opportunity to invest in alternative proven and cost effective health interventions.

Several organisations have considered developing programs and processes for disinvesting health interventions of limited benefit. However, in the face of established use, it is not an easy process to change clinical practice even when there is evidence of clinical ineffectiveness.

### National scenario

National and state mechanisms for evaluating and aiding the introduction and diffusion of new health interventions exist (eg. MSAC, PBAC, VPACT), but there are few mechanisms for disinvesting health interventions that offer no or low health gain. Both MSAC and the PBAC have the capacity to disinvest such interventions (vis a vis by removing items from the MBS and PBS, respectively).

At its May 2006 meeting, MSAC noted that, in relation to the withdrawal of public funding, withdrawing a service that is already funded would require evidence that the procedure was either unsafe, or not effective (particularly where there are other procedures/technologies that are more effective) or well outside the acceptable level for cost effectiveness. MSAC is yet to disinvest/delist any item from the MBS or the PDL.

The PBAC has, to date, been proactive in delisting items from the PBS only after an item is approved for purchase over the counter and when this is cheaper than purchasing it via a prescription. Almost all the items delisted from the PBS have been as a result of pharmaceutical companies voluntarily withdrawing them as a result of newer, more effective being listed.

### Jurisdictional scenario

In Victoria, the DHS Advisory Committee on Access to Elective Surgery (ACAES) Appropriateness Sub-Committee is developing criteria for placing patients on waiting lists for procedures where conservative management would reduce the volume and inform conservative therapy. It may be that VPACT could provide support for this process through commissioning evidence reviews to inform policy and practice.

At least one public health service in Melbourne has considered processes for disinvesting health interventions that offer no or low health gain. This will be discussed at the workshop.

In its *Waiting time and elective patient management policy* (2006), NSW Health specifies a range of cosmetic and discretionary surgical procedures, tabulated in the following table, that should not routinely be performed in public hospital in NSW unless there is a clear need to improve a patient's physical health.

Cosmetic Procedure Exception	Cosmetic Procedure Exception
Bilateral breast reduction	Severe Disability due to breast size
Hair transplant	Disfiguring Hair loss due to Severe Burn
Reduction of upper or lower eyelid	Severe Visual Impairment
Total rhinoplasty	Major Facial Trauma Congenital abnormality - paediatrics
Liposuction	Nil
Abdominal lipectomy	Nil
Bilateral breast augmentation	Nil
Facelifts	Nil
Correction of bat ear (>16 years old)	Nil
Tattoo removal procedures	Nil
Candela Laser	Congenital abnormality - paediatrics < 17 years
Discretionary Procedure	Exception
Gender reassignment surgery	Congenital abnormalities in children
Lengthening of penis procedure	Congenital abnormalities in children
Insertion of artificial erection devices	Nil
Reversal of sterilization	Nil
Social circumcision	Nil

## International scenario

In the United Kingdom (UK), the National Institute for Health and Clinical Effectiveness (NICE) has recently developed advice about disinvesting treatments which are in common use despite poor evidence of clinical effectiveness, or which could be more selectively used, thus freeing up resources for improvements in patient services. NICE issues reminders of recommendations, to be read in conjunction with the NICE guidance in which the recommendation appears, to help the NHS reduce ineffective practice. However, there are few of these and appear to be non-controversial as they represent minor aspects of providing health technology or practice.

Also in the UK, some NHS Trusts (analogous to health services comprising several hospitals), which are responsible for allocating funds and providing health services via GPs and hospitals, are considering identifying health technology or practice for disinvestment. One such example is the South Birmingham Primary Care Trust, which, from 1 October 2006, has not routinely funded a number of procedures, including arthroscopic debridement and washout, insertion of grommets and spinal cord stimulation for chronic pain (refer Appendix 3).

The identified procedures were intended to help control demand from patients for procedures that were not considered appropriate and to assist GPs in challenging patient expectations and to improve the quality of patient care. A blanket ban on funding of these treatments does not exist; a panel existed to consider recommendations where such procedures would be of clear benefit to their patients.

In New Zealand, the National Advisory Committee on Health and Disability (2006) identified that while it is very hard to disinvest (cease funding services that have historically been funded), disinvestment is often the prerequisite to having the resources to fund new interventions. A frequent comment was that in District Health Boards, prioritisation often occurs at the margins (i.e. decisions about small pools of funding) rather than around baseline funding. One of the reasons for this is what is already being provided tends not to be negotiable when funding decisions are being made.

It has to be said that consideration needs to be given to any discussion regarding the disinvestment of health technology or practice and the subsequent appropriate and adequate 'disimplementation'. It must be iterated that 'blanket' disinvestment of a technology or clinical practice may not only be impractical, but possibly inappropriate, particularly in situations where there are no other treatment options.

Disinvestment of health interventions that offer no or low health gain is a policy challenge that requires attention, both for quality of care and sustainable resource allocation. With metropolitan and regional health services undertaking local changes there is an opportunity to drive more systemic reform.

## Opportunities arising

Key opportunities arise for disinvesting health interventions that offer no or low health gain, including development of guidance and protocols to assist health services discontinue their use. Principle benefits resulting from disinvesting health services of health interventions could include:

- Increasing patient safety and quality of care
- Reduction in unnecessary referrals
- Optimising availability of resources for appropriate patients
- Ensuring appropriate patients receive treatments promptly
- Ensuring that only proven, clinically effective and cost effective health interventions are undertaken
- Improving efficiency
- Potential savings from reduced costs associated with undertaking inappropriate health interventions and reduced waiting lists.
- Reduced costs associated with health services independently implementing new technology (i.e. improved purchasing power)
- Reduced cost associated with reducing the introduction of clinical practices that do not meet appropriate effectiveness criteria.

## **Challenges for disinvesting technology and clinical practice**

- How do the different stakeholders (i.e. clinicians, health service managers, consumers, policy makers) view or define a health intervention that offers no or low health gain?
- Developing agreed criteria for health interventions that offer no or low health gain
- Identifying health interventions that offer no or low health gain
- Prioritising these health interventions
- What consideration should be given to inform a decision to disinvest?
- What processes, strategies or frameworks to be developed to support such a decision?
- What would these consider/comprise?
- Buy in from clinicians and health services affected by 'disimplementing' (and professional bodies?)
- Incentives for clinicians and health services to 'disimplement'
- Who/how should such a disinvestment be managed? And by whom?
- What resources would be required to support stakeholders in this venture?
- Assurance that any savings are reinvested to support appropriate uptake and diffusion of new technology or clinical practice that pleads to improved health outcomes
- Quantifying outcomes associated with disinvesting these health interventions

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## Appendix 1

### Commonwealth Government response to *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business (2006)*

#### Social and environmental regulation

##### Health and health-related regulation

###### Therapeutic products and medical devices

###### **Recommendation 4.17: Develop the regulatory framework for the ANZTPA in accordance with COAG principles**

The Australian Government should ensure that the regulatory framework and supporting legislation for the Australia New Zealand Therapeutic Products Authority are developed and implemented in accordance with the principles agreed by COAG for good regulatory practice, particularly in relation to industry consultation.

###### **Response**

The Australian Government agrees to the recommendation. In line with the principles agreed by the Council of Australian Governments (COAG) in the “Principles and Guidelines for National Standard Setting and Regulatory Action” the regulatory framework and legislation for the ANZTPA is being developed to minimise the regulatory burden on industry while at the same time meeting ANZTPA’s objective to safeguard public health and safety in Australia and New Zealand.

In addition, the joint regulatory scheme is being developed in accordance with the principles outlined in a number of agreements between the two countries.

Extensive consultation with stakeholders has occurred and will continue to occur at all critical stages in the development of the joint regulatory scheme. The Therapeutic Products Interim Ministerial Council (the Council) announced in December 2005 that an anticipated 1 July 2006 start date for the ANZTPA had been deferred to allow for an extensive consultation program to enable industry, in particular, to review and comment on the legislation and rules for the new Authority. In May 2006 the Council announced that the proposed joint regulatory scheme for therapeutic products is expected to begin in the second half of 2007.

###### **Recommendation 4.18: Improve domestic regulatory arrangements for therapeutic products and medical devices**

The Australian Government should improve existing domestic regulatory arrangements for therapeutic products and medical devices, particularly by:

- rationalising amendments to the Therapeutic Goods Act, together with the supporting orders, codes, standards and determinations and guidelines issued by the Therapeutic Goods Administration, and
- removing requirements specific to Australia unless they can be fully justified.

## Response

The Australian Government agrees to the recommendation and is addressing the recommendation as part of the development of the joint regulatory scheme to be administered by ANZTPA. As part of this process all regulatory requirements will be the subject of extensive industry consultation (see response to Recommendation 4.17). Any requirements specific to Australia (and/or New Zealand) will need to be consistent with the objectives of the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products. The objectives of this Agreement state clearly that the joint regulatory scheme must be developed and maintained in accordance with international best practice. Consequently in the lead up to the commencement of the ANZTPA it is not anticipated that the Therapeutic Goods Administration will be making significant amendments to the Therapeutic Goods Act 1989, supporting orders, codes, standards and determinations and guidelines.

### **Recommendation 4.19: Allow choice of certification body for medical device manufacturers**

The Australian Government should consider allowing Australian manufacturers to choose a certification body (acceptable to the Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures (having regard to the recommendations of the Medical Devices Industry Action Agenda).

## Response

The Australian Government agrees to the recommendation. The Medical Devices Industry Action Agenda has been considering this issue. The Action Agenda was recently announced and, as part of the implementation phase, the Action Agenda Implementation Group will consider best practice regulation for devices and will propose desirable changes to regulatory practices that also ensure safety, timeliness and transparency.

### **Recommendation 4.20: Apply an internationally agreed definition of the central circulatory system for medical devices**

The Australian Government should apply an internationally agreed definition of the central circulatory system to all applicable medical devices.

## Response

The Australian Government agrees to the recommendation. The Global Harmonization Task Force (GHTF) is considering this issue. The GHTF is a group of representatives from national medical device regulatory authorities and the regulated industry from the European Union, the United States, Canada, Japan and Australia. Once GHTF have finalised/agreed a definition TGA will consult with industry.

The timeline is dependent on GHTF processes.

**Recommendation 4.21: Streamline change of sponsor procedures for new medical devices**

The Australian Government should, in establishing the Australia New Zealand Therapeutic Products Authority, address the concerns of the medical device industry about the procedures for change of sponsor of new medical devices.

**Response**

The Australian Government agrees to the recommendation.

In response to concerns regarding transfer of sponsorship arrangements, the Australian Government, through the Therapeutic Goods Administration (TGA), has agreed to develop an administrative process to facilitate transfer of applications to a new sponsor.

Discussions are being held with industry to implement revised arrangements ahead of the establishment of the Australia New Zealand Therapeutic Products Authority.

**Recommendation 4.22: Review health technology assessment procedures**

The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.

**Response**

The Australian Government agrees to the recommendation while continuing to support cost effectiveness methodologies. The medical device industry has considered these matters in depth through the Medical Device Industry Action Agenda. The Action Agenda was recently announced and the Action Agenda Implementation Group will consider best practice health technology assessment for devices and will contribute to the system-wide review. Work underway to enhance the efficiency and transparency of current processes will continue during this time.

## Appendix 2

### Victorian policy advisory committee on clinical practice and technology

#### VPACT Terms of Reference

#### Background

The Victorian Department of Human Services (department) established the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) to consider and make recommendations regarding the application of new and existing technologies and clinical practices in Victorian public health services and hospitals. This includes identifying, prioritising, introducing, evaluating and ongoing monitoring of new and existing technologies and clinical practices.

The Australian Government established the Health Policy Advisory Committee on Technology (HealthPACT), comprising jurisdictional representation, to advise the Australian Health Ministers' Advisory Committee and the Medical Services Advisory Committee (MSAC) on the introduction of new and emerging technology into the Australian health care system.

HealthPACT has oversight of the Horizon Scanning Unit (HSU), whose role is to identify and undertake assessments of new and emerging technologies. The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIPS), a programme of the Royal Australasian College of Surgeons, and NET-S contribute to this process.

The activities of VPACT will complement and supplement those being undertaken by HealthPACT. It will address Victorian specific issues and utilise HealthPACT information where available. From time to time, VPACT may also sponsor work on behalf of HealthPACT. VPACT will also consider good practice management of medical and surgical supplies regarding the use of new or existing technologies or clinical practices.

The scope of technology and clinical practice to be considered comprises all types of clinical diagnostic or treatment interventions including prostheses, implantable devices, diagnostic tests, medical and surgical procedures and high-cost pharmaceuticals. The Victorian Medicines Advisory Committee is being established to specifically consider other pharmaceuticals as well as the quality use of medicines and they may, from time to time, seek advice from VPACT.

#### Role and function

VPACT has been established to enable a systematic approach to the introduction and use of new and existing technologies and clinical practices in public health services in Victoria. Its role is to advise and make recommendations on:

- Mechanisms for early identification of new technologies and clinical practices with potential implications for public health services
- Assessment of clinical and cost effectiveness of new and existing technologies and clinical practices
- Establishment of Nationally Funded Centre Program applications
- Priorities for the introduction and use of new technologies and clinical practices
- Policies and procedures around the best practice for introduction and use of new and existing technologies and clinical practices in public health services
- Policies about new or modified health service delivery as required by introduction of new or changed technology
- Requirements for evaluating and monitoring the introduction and use of new technologies and clinical practices in public health services
- Dissemination of information on the introduction and use of new and existing technologies and clinical practices.

VPACT will also liaise with the following:

- Victorian Medicines Advisory Committee (VMAC)
- Established committees in Victorian health services that consider the assessment and adoption of new technologies and clinical practices within their institutions
- HealthPACT and MSAC on the introduction of new and emerging technology in the Australian health care system
- The National Institute for Clinical Studies
- Established committees in other jurisdictions providing advice on introducing new technology and clinical practice
- Other Health Technology Assessment agencies nationally and internationally, such as Health Technology Assessment international (HTAi) and International Network of Agencies for Health Technology Assessment (INAHTA).

The principles underpinning the deliberations and recommendations of VPACT are:

- Health and safety for patients, clinicians and the community is paramount.
- Broad-based stakeholder consultation is considered.
- Ethics procedures are in place to protect patients, clinicians and the community.
- Appropriate institutional committees approve technology for use.
- Evidence-based practice informs conditions and logistics for introduction.
- Patient information and informed consent procedures are established.
- Appropriate and credentialed and trained staff in place to assist with new technology introduction.
- Risk management procedures are in place to reduce adverse events.
- There is no conflict of interest between a provider and technology supplier.

## Membership

VPACT will provide information, advice and knowledge to assist with the introduction and use of new and existing technologies and clinical practices in the public sector. Ideally, it will encompass knowledge and expertise about:

- Health technology assessment
- Health service delivery
- Health policy
- Quality and safety
- Evidence-based review and clinical practice
- Population health
- Health economics
- Clinical pharmacology
- Clinical medicine
- Consumer advocate/s

- Senior health service management
- Senior Medical Advisor, Programs Branch, DHS.

Membership will also include representation from a public health service Technology/Clinical Practice Committee.

The term of appointment of the chair and members will be for two years in the first instance, except for the senior health service manager, who will rotate annually, and the Senior Medical Advisor, Programs Branch. Members who do not attend at least three meetings per annum will automatically lose their membership unless extenuating circumstances can be proven. Substitution of appointed members will not be permitted. Members will be appointed for a maximum of two two-year terms.

### **Conflict of interest and confidentiality**

VPACT members must ensure that any real or potential conflict of interest arising in regard to any matter under discussion by VPACT is made known at the commencement of each VPACT meeting, particularly when considering submissions from health services/hospitals where members practise. Where discussion ensues on a matter in which the VPACT member has declared a real or potential conflict of interest, the VPACT member will comply with the identified method of addressing any such conflicts, which requires him/her to absent himself/herself from participation in that discussion.

VPACT members must ensure that any information acquired or created for VPACT consideration is only used for performing duties as a VPACT member. Members may not use their knowledge of confidential VPACT issues to provide inequitable benefit gain or advantage to any individual, private or public organisation or group.

### **Meetings**

VPACT will meet up to four times per annum depending on the number and scope of issues and initiatives being addressed. Clinical experts may be invited to attend VPACT meetings and contribute to its activities. Decisions of VPACT will be made by consensus. If consensus is not possible, a majority will suffice. For a decision or recommendation, a quorum will comprise half of all VPACT members plus one.

Applicants making submission to VPACT are not to canvas VPACT members and would not routinely be invited to present to VPACT.

### **Challenge of VPACT recommendations**

Applicants who wish to challenge a VPACT recommendation should present their case in writing within 60 days of receiving written notification of the decision. A challenge should be endorsed by the Chief Executive Officers of all health services/hospitals that participated in the submission to VPACT. The department will seek to clarify the issues; actions may include seeking further independent expertise and, if appropriate, further review by VPACT.

## **Reporting/notification of VPACT recommendations**

After VPACT makes its recommendations, departmental endorsement of the recommendations is sought through the Executive Director, Metropolitan Health and Aged Care Service. Following endorsement, the department will contact the lead applicant and arrange a meeting to consider costs, monitoring requirements, reporting requirements and a plan for implementing the new technology/clinical practice.

## **Operations**

Time-limited panels may be formed to oversight particular projects or assemble advice on a specific issue. Such panels: will be chaired by a VPACT member, may coopt independent members, may seek other expert opinion in pursuit of information and will report to VPACT. External consultants may be contracted by the department to undertake a review of new technology/clinical practice to inform VPACT consideration. VPACT will oversight this process.

## **Secretariat**

Programs Branch, Metropolitan Health and Aged Care Services Division, Department of Human Services, will provide secretariat support for VPACT.

## Appendix 3

### South Birmingham Primary Care Trust Commissioning Policy (October 2006)

#### Procedures not routinely funded

From 1 October 2006, South Birmingham's health commissioners will no longer routinely fund the following procedures:

#### Elective surgical procedures

##### Aesthetic surgery

- Abdominoplasty or liposuction
- Breast enhancement other than following essential surgery
- Laser cosmetic surgery
- Removal of lipoma, sebaceous cysts and other minor skin lesions
- Pinnaplasty

##### Ganglion removal

- Ganglia of the wrist where there is no neurovascular compromise
- Painless seed ganglia at the base of the digits
- Mucoid cysts arising at the DIP joint unless nail growth disrupted or tendency to discharge

##### Orthopaedic surgery

- Diagnostic arthroscopy of the knee
- Arthroscopic debridement and washout
- Spinal fusion or facet joint injections (for chronic back pain)

##### Inguinal Hernia

- Primary repair by laparoscopic surgery

##### ENT

- Insertion of grommets
- Tonsillectomy

##### Oral surgery

- Dental implants
- Wisdom teeth removal

##### Gynaecology

- Dilatation and curettage for menorrhagia in women under 40 years of age
- Hysterectomy for menorrhagia

##### Sexual dysfunction

- Gender reassignment surgery
- Penile implants

## Varicose Veins

### Other elective procedures

#### Chronic pain

- Spinal cord stimulation for chronic pain

#### Hyperbaric oxygen treatment

#### Mental health

- Inpatient treatments to address behavioural issues such as addiction (e.g. alcoholism)
- Therapeutic community method of treating borderline personality disorder

#### Please note

This policy does not mean that these procedures will not be available to anybody. These procedures have been classified as “Not Routinely Funded” because the link between procedure and benefit to patients is not strong.

If a GP or hospital specialist believes that their patient can definitely benefit from one of these procedures they are invited to apply to the Primary Care Trust’s Special Cases panel (some of the procedures listed are already dealt with in this way):

Special Cases Panel secretariat  
 South Birmingham PCT Contracts Department  
 8th Floor, Triplex House, Eckersall Road  
 Kings Norton, Birmingham  
 B38 8SR

The PCT will work with clinicians to develop a streamlined process for applications including agreement of criteria that will normally allow patients access to a treatment that is not routinely funded (see example below).

#### Example of criteria for eligibility: insertion of grommets

- Insertion of grommets will normally be approved when ‘glue ear’ persists for more than six months and the child suffers from one of the following:
  - 5 or more recurrences of acute otitis media in a year
  - Delay in speech development
  - Educational problems
  - Behavioural problems
  - A second disability such as Down’s syndrome
  - Severe collapse of the eardrum

