Supp Sub No. 12.2
Date Received: 28/07/14

ANSWERS TO QUESTIONS ON NOTICE to THE DEPARTMENT OF HEALTH

INQUIRY INTO SKIN CANCER IN AUSTRALIA
July 2014

1. **Participants in the inquiry have told the Committee about the need to up-skill general practitioners in skin cancer medicine in order to improve diagnostic accuracy and reduce costs from over-diagnosis.**
   a. **What options are available to the Commonwealth Government to encourage more doctors to use dermatoscopes and undertake further training in skin cancer medicine?**
   b. **Approximately how much would each of these options cost?**

ANSWER:

All registered medical practitioners in Australia are required to participate regularly in continuing professional development that is relevant to their scope of practice in order to maintain, develop, update and enhance their knowledge, skills and performance to ensure that they deliver appropriate and safe care.

The requirements for general practitioners are determined by the Royal Australian College of General Practitioners and the Australian College of Rural and Remote Medicine. The Department has no role in determining these requirements.

Through the Rural Health Continuing Education Programme, the Department provides targeted funding assistance for rural health practitioners to access CPD. Grants are provided to support either direct access to CPD by eligible individuals or groups, or the provision of CPD to them by organisations. Priority is given to funding gaps in existing arrangements and supporting initiatives that are demonstrated by evidence-based research as needing urgent intervention.

The committee may wish to seek the advice of the Royal Australian College of General Practitioners and the Australian College of Rural and Remote Medicine on the CPD opportunities they offer with respect to skin cancer medicine, and the costs of such training. Note that CPD costs are already able to be claimed as a tax deduction by an individual doctor, where the training relates to their work.

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2. **The committee has heard a range of views from inquiry participants on the role of skin cancer clinics in providing a skin cancer-focused primary care option to patients. Does the Commonwealth Government have the authority to regulate minimum standards of training for doctors working in skin cancer clinics or self-described as 'skin cancer doctors'? Through what mechanism could this be achieved?**

ANSWER:
The Commonwealth government does not have the direct authority to regulate standards for the training of doctors. The National Registration and Accreditation Scheme is established through the *Health Practitioner Regulation National Law Act 2009* (the National Law). The legislation is enacted in each state and territory. It is not Commonwealth legislation. Under the legislation, the Medical Board of Australia (MBA) is responsible for all matters relating to the registration and regulation of the medical profession in Australia and is independent of Government.

Under the National Law, all Health Ministers provide oversight and may give directions to the Australian Health Practitioner Regulatory Agency (AHPRA) that supports the MBA about policies to be applied by the National Law, however they cannot give direction about a particular qualification.

Under the National Law, it is an offence for a medical practitioner to hold him or herself out as a medical specialist, in this case a dermatologist, if he or she is not registered as such by the MBA. The title 'skin cancer doctor' is not protected. If there are concerns that a medical practitioner is providing services which are outside the scope of his/her practice, AHPRA should be notified of the issue to allow for assessment of the practitioner's practice and to ensure safety of the public.

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3. The committee has heard evidence (for example, from Cancer Council Western Australia on 1 May 2014) suggesting that there is an overuse of vitamin D testing in Australia when taking into account the lack of scientific consensus on the levels required.

a. What is the most recent data on the total cost to the Medicare Benefits Schedule of vitamin D testing, and how much does each individual test cost?

ANSWER:
The Medicare Benefits Schedule provides rebates for two items:

66608	Vitamin D or D fractions - 1 or more tests **Fee:** $39.05 **Benefit:** 75% = $29.30 85% = $33.20
66609	A test described in item 66608 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18) **Fee:** $39.05 **Benefit:** 75% = $29.30 85% = $33.20

The number of MBS claims for vitamin D testing has increased each year over the past ten years, from 117,474 services in 2003/04 to 4,331,030 claims in 2012/13.
Over the same time period, a similar increase was seen in benefits paid, which rose from $4,256,772 in 2003/04 to $151,129,505 in 2012/13. The vast majority were bulk billed services (97% in 2012-13)

3b. Is there evidence that vitamin D tests are being ordered routinely for patients receiving blood tests, even if deficiency is not necessarily suspected?

ANSWER:
In 2012, in response to the rapid increase in utilisation and a corresponding growth in MBS expenditure, the Department of Health commissioned a review of the MBS items relevant to vitamin D testing to ensure that the items reflect contemporary evidence, are used appropriately in clinical practice to improve health outcomes for patients, and represent value for money.

The Review found that there has been a substantial increase in the number of claims for vitamin D testing over the past ten years, largely generated by GPs and other medical professionals providing GP services for the purposes of screening or testing, rather than limited to those at high risk. It was found that 98% of vitamin D tests were regularly requested with other MBS items used for routine screening testing, while only 1.7% of tests were requested specifically for vitamin D purposes. Australian and international clinical practice guidelines recommend targeted vitamin D testing for patient populations who are at high risk of vitamin D deficiency. However, routine screening is not recommended for low risk populations.

3c. Could MBS subsidisation of vitamin D tests be limited to instances where the doctor has reasons to suspect deficiency? How would this be regulated and enforced?

ANSWER:
The 61st Medical Services Advisory Committee (MSAC) meeting considered the Review findings. After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of vitamin D testing, MSAC recommended that the item descriptors for Vitamin D testing items be amended to limit access to patients with specific conditions.

MSAC is an independent expert committee that advises the Minister for Health about whether a medical service should be publicly funded based on an assessment of its safety, effectiveness and cost effectiveness, using the best available evidence. This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for both patients and taxpayers. This recommendation is currently being considered.

The Royal College of Pathologists Australasia (RCPA) released a Position Statement in May 2013 for the use and interpretation of Vitamin D testing. The Royal College of General Practitioners guidelines also cover appropriate use of Vitamin D testing.

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4. **Many participants in the committee's inquiry have suggested action is needed to raise public awareness about skin cancer risk factors and the need for high risk individuals to regularly have their skin checked. Suggestions to achieve this include an early detection campaign to educate people on how to recognise suspicious lesions, encourage people to know their individual risk of developing skin cancer (e.g. based on age, history, skin tone), and to encourage those at high risk to visit a doctor for a skin check. If a widespread early detection campaign was implemented, what would be the estimated cost to the Medicare Benefits Schedule of an increase in GP consultations associated with such a campaign?**

ANSWER:
GPs and specialists already have access to a range of Medicare Benefit Schedule items that allow for discussions with patients across a range of issues, including the importance of skin cancer checks. For example, using the GP general consultation items, a GP will undertake a range of clinical tasks including examinations, investigations and the development of management plans which may include, if appropriate, the development of preventive health care strategies such as educating patients about skin cancer and the importance of regular checks for those at risk.

The extent to which a national campaign to increase awareness of skin cancer would result in an increase in GP consultations is difficult to assess, and would depend on the nature and scope of any such campaign. In many GP consultations patients present with a range of issues. However, if patients with no other reasons to attend their GP were encouraged, and did, attend their doctor as a result of the campaign then there could potentially be some increase in GP consultations.

5. The committee has received evidence (for example, from the Australian Melanoma Research Foundation on 14 April 2014) about the toxic side effects and limited efficacy of some new drugs that have entered the market for advanced melanoma. What processes does the Therapeutic Goods Administration use to ensure that side effects and overall efficacy are taken into account before approving a new drug?

ANSWER:
All medicines carry a risk of producing adverse reactions in some patients. Likewise, for some medicines, there is a risk of limited efficacy. Products carrying a higher risk, including all prescription medicines, receive a higher degree of pre-market assessment and, where the benefits of taking the medicine outweigh the risk of adverse reactions, are registered on the Australian Register of Therapeutic Goods (ARTG). An example might be the approval of a new cancer medicine for a target population where it is known the medicine is likely to result in relatively severe side effects.

To enable a prescription medicine to be marketed in Australia, a sponsor is required to submit an application accompanied by scientific and clinical data to support the quality, safety and efficacy of the product for its intended use.

Data fall into the following main categories; (i) chemistry and manufacturing control, (ii) toxicity and (iii) pharmacology and clinical use. The data is evaluated and scientific reviews are prepared on each of these areas.

As part of the assessment process for most new medicine applications, the TGA delegate also seeks advice from an independent expert advisory committee, the Advisory Committee on Prescription Medicines.

The delegate, usually a senior medical officer, considers the overall application, including the evaluation reports, the advice from the expert committee as well as the risk benefit profile of the medicine, and either approves the application to include the medicine on the ARTG or rejects it.

Once a therapeutic product is approved, the TGA continues to monitor the product in the market. This type of risk management aims to continually monitor and evaluate the safety and efficacy (performance) profile of the medicine, device or biological and to manage any risks associated with individual products.

TGA's risk management approach consists of an integrated set of tools that work together to protect the health and safety of Australians. This includes tools for information collection, monitoring, evaluation, and risk management from the development stage through to initial marketing and continued supply of a therapeutic product in Australia.

6. The committee has heard from several inquiry participants (for example, from the Peter MacCallum Cancer Centre on 6 June 2014) that there is a need to speed up the TGA approval and PBS listing processes for new cancer drugs that have already been made available overseas. The committee has also heard about innovative approaches being used in some countries to enable rapid access to certain drugs, for example, by tying government subsidies to proven outcomes.

a. What innovative approaches are being taken in Australia to promote earlier access to certain drugs, and how extensively are these approaches being used?

b. How is patient Safety and cost effectiveness taken into account in these approaches?

ANSWER

Regulation

The TGA has a continuous improvement program to streamline the registration process and is exploring options to provide a more flexible process for market authorisations in Australia.

For various reasons there are times when approved products on the ARTG may not meet the needs of all patients and there are provisions for this under the Therapeutic Goods Act 1989.

In Australia, the Special Access Scheme (SAS) and Authorised Prescriber schemes allow doctors and patients rapid access to unregistered medicines, where such use is medically required.

The SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. The SAS allows for seriously ill patients to access unapproved products through either a notification of use or by an application by medical practitioners made to the TGA which are assessed on an individual basis with consideration being given to evidence of the safety (whether it will cause harm) and efficacy (whether it will provide benefit) of the product and the seriousness of the condition being treated. Medical practitioners are aware of the workings of the SAS.

All applications for access to unapproved medicines are taken very seriously by the TGA and acted on as quickly as possible. A doctor can also apply to the TGA for approval as an 'Authorised Prescriber' for the purpose of supplying medicines that have not been fully assessed by the agency.

Australian patients are also able to access unapproved medicines through clinical trials. The Clinical Trials Notification (CTN) and Clinical Trials Exemption (CTX) schemes provide two avenues through which unapproved therapeutic goods for use in clinical trials may be lawfully supplied. The choice of which scheme to follow (CTN or CTX) lies firstly with the trial sponsor and then with the Human Research Ethics Committee (HREC) that reviews the trial protocol.

Reimbursement

In Australia, assistance with the cost of prescription medicines is provided through the Pharmaceutical Benefits Scheme (PBS).

Australia has one of the fastest reimbursement processes for Australian Government subsidy of medicines in the world, with the Pharmaceutical Benefits Advisory Committee (PBAC) cycle taking 17 weeks from application to assessment.

In making recommendations to list medicines, the PBAC uses best practice evaluation methods to consider their clinical and cost effectiveness, including the potential benefit and total cost of the listing to the Australian community.

A medicine cannot be included on the PBS unless the PBAC recommends to the Australian Government that it be listed. Therefore, a positive PBAC recommendation is a very important step in the listing process. However, other steps generally need to be taken before a listing is achieved, such as pricing negotiations with the product's sponsor, finalisation of the conditions for listing, quality and availability checks and consideration by the Australian Government.

There are approximately 100 cancer treating medicines available on the PBS, costing the Australian Government close to $1.2 billion a year in expenditure. The Abbott Government has listed a further eight medicines to treat cancer since September 2013 - dabrafenib (Tafinlar®), gefitinib (Iressa®), sunitnib (Sutent®), erlotinib (Tarceva®), denosumab (Xgeva®), panitumumab (Vectibix®), an extension to the listing of temozolomide (Temodal®) and everolimus (Afinitor®).

With respect to the timelines there can be many reasons why the time taken for PBS listing of a medicine may vary, such as:

- the drug manufacturer may decide not to make a submission to the PBAC to list their medicine on the PBS following approval from the TGA;
- the PBAC may reject the submission for PBS listing due to the application not being clinically effective or cost effective from the evidence provided;
- the drug manufacturer may also decide not to progress PBAC recommendation to list the medicine on the PBS; and
- the drug manufacturer may not be satisfied with the PBAC recommendation (can be due to agreed priced offered or other pricing arrangements) and may pursue to reapply to the PBAC for further consideration.
    - For example – the PBAC recommended the PBS listing of bevacizumab for the treatment of advanced epithelial ovarian, fallopian or primary peritoneal cancer. The sponsor did not accept this recommendation and submitted an application to the March 2014 PBAC.
    - For example, abiraterone (Zytiga®) for the treatment of advanced prostate cancer was recommended by the PBAC on three occasions before the sponsor company accepted the recommendation.

Further, Australia's pharmaceutical regulatory and reimbursement processes have evolved to keep pace with the changing needs in the community, to provide additional mechanisms to expedite access like the managed entry scheme, parallel processing and risk share agreements. For example, the development of parallel processing arrangements now mean that a company can progress an application for regulatory approval through the Therapeutic Goods Administration at the same time as an application being considered for Australian subsidy by the PBAC.

These existing processes already enable the collection of 'real world data' post listing to inform the PBAC's recommendations. For example, Yervoy® (ipilimumab) for metastatic melanoma was listed on the PBS on 1 August 2013 using the managed entry scheme. This provided expediated access to the medicine while effective data continues to be collated. The Public Summary Documents for this medicine are publicly available at www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-11/ipilimumab

The PBS listing of Taflinlar® (dabrafenib) for advanced melanoma on 1 December 2013, occurred only 96 days after regulatory approval by the TGA. This medicine was recommended at the July 2013 PBAC meeting – further information about the PBAC's recommendation of the medicine can be found on the PBS website at www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/dabrafenib

More recently, the Australian Government has further reduced administrative burden and red tape for companies with the removal of the requirement for Pharmaceutical Benefits Pricing Authority consideration, allowing them to have more time to prepare pricing applications to the Department of Health. This commenced following the March 2014 PBAC meeting.

Cancer care is a complicated and sensitive area, and the system continues to evolve to deal with new technologies and changing approaches to gathering evidence to support reimbursement. This is an issue all international regulatory and reimbursement bodies are dealing with.