MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED
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Submission to the Senate Standing Committee on Finance and
Public Administration Inquiry into the Government's Administration
of the Pharmaceutical Benefits Scheme (PBS)
15 July 2011

Introduction:

The Medical Oncology Group of Australia Incorporated (MOGA), the peak national, professional organisation representing Australian medical oncologists and the medical oncology profession, welcomes the Senate Standing Committee on Finance and Public Administration Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme (PBS). The Association has and continues to work closely with the various regulatory agencies including the Pharmaceutical Benefits Advisory Committee (PBAC), the Department for Health and Ageing (DOHA), key consumer groups as well as the pharmaceutical industry, to achieve important changes in the national supply, subsidy and access arrangements for oncology drugs and treatments.

The Association has previously written to the Prime Minister and the Minister for Health to express our concerns regarding the Federal Cabinet decisions to delay the listing of medicines referred by the PBAC on the PBS, and, therefore fully supports this timely Senate Inquiry.

This inquiry provides an opportunity for MOGA to present recommendations to address a range of recent professional concerns and to assist in the development of a more responsive, effective, timely and transparent process for the listing of medicines on the PBS to benefit clinicians, patients and the national health infrastructure.

Our response to the inquiry Terms of Reference, are as follows:

a) The deferral of listing of medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee: The Association wrote to DOHA in response to the Media Release of February 25, 2011 on the decision to defer the listing of oxycodone/naloxone (Targin®) and the subsequent determination to defer the listing of cetuximab (Erbitux®) on the PBS.

The Federal Government's 25th February decision to defer indefinitely the listing of eight new medicines and vaccines, including oxycodone/naloxone, on the PBS, "for conditions where existing treatments are already available…", is of concern to our Association as follows;

- While medicines that exceed a cost to Government of more than $10 million a year are reviewed by Cabinet, in this case Cabinet intervened in the listing of medicines that fall well below that threshold. The criteria used for the Cabinet decision-making process are unknown, as is the deferral period.

- The Cabinet intervention contradicts the recommendation of the Government's clinical and health economics expert committee (the PBAC) that the medicines and vaccines are cost-effective, should be subsidised on the PBS and gained pricing approval from the Pharmaceutical Benefits Pricing Authority. This is the first time Cabinet has not accepted a positive recommendation by its own clinical and health economics experts.

- This Cabinet action ignored the established process for pharmaceutical assessment by the PBAC. No satisfactory explanation has been given for this decision beyond short-term budgetary considerations.

- It is of great concern that the Government has rejected the advice of the PBAC and questions the basis on which Cabinet would overthrow recommendations made by its own expert committee as well as the future role and authority of the PBAC.

b) Consequence to patients of such deferrals: The Association is concerned at the recent decisions by Cabinet to defer PBS listing of medicines that are critical to the welfare of patients with chronic conditions, including people living with severe persistent and disabling pain. The Association has specific concerns in relation to two of the deferred medications: oxycodone/naloxone combination compound and cetuximab.

MOGA strongly recommends the immediate PBS listing of oxycodone/naloxone because of its unique clinical profile which provides benefits to patients, including some 60% of people with cancer, and many others who suffer severe, disabling, chronic pain not associated with other pain medications. Oxycodone/Naloxone is a powerful pain relief oral medication, which is a fixed combination, administered in a prolonged release lasting 12 hours per dose: the drug prevents/reduces adverse drug reaction and the antagonistic effect deters abuse. [1.]

In July 2010, the PBAC recommended cetuximab (Erbitux®) be listed on the PBS following failure of chemotherapy in patients with advanced KRAS wild-type bowel cancer, at a cost to the Government of approximately $30 million a year. This measure would provide a subsidy that would benefit approximately 2220 eligible patients by reducing out-of-pocket costs to a maximum of about $34.20 or less per script. Although Cetuximab currently costs patients approximately $2,000 per week, its use is restricted to approximately 60 % of patients with colorectal cancer. The PBAC's positive recommendation followed on from consideration of five years of submissions from March 2005, when cetuximab was first made globally available as a treatment for colorectal cancer.[2.]

As part of the new agreement with the pharmaceutical industry that came into effect on 1 January, the Federal Government committed to make a decision on positive PBAC recommendations within a maximum 6 month timeframe. Cetuximab was one of the first test cases of this agreement and the Government's failure to make public its decision on this oncology drug within this timeframe, has caused additional concern amongst medical oncologists and their patients as follows;

- Government has again failed to take the advice of its own independent panel of expert clinicians and health economists, the PBAC. The delay in the funding and listing of cetuximab on the PBS is stated as due to the Medical Services Advisory Committee (MSAC) and delays in finalising the price of the Medicare Benefit for KRAS testing. Although Merck Serono did not apply for a Medicare rebate for the gene test until October, PBAC approved Cetuximab for subsidy last July and on December 3 MSAC advised Government to fund the test but, to date, the decision on the test price still rests with the DOHA. We strongly recommend that this matter be urgently addressed and are of the view that drugs/treatment and associated test approvals should be undertaken simultaneously.

- MOGA believes that the national oncology drug and treatment approval, subsidisation and access process is out of step, lagging behind emerging clinical research and developments in clinical practice. These developments should be addressed with a more timely and proactive approach, affording patients and clinicians with the benefits of the rapid update of international best practice as described below:-

  1) Cetuximab does not fall into the category of oncology treatments that can be deferred. Cetuximab is indicated for the treatment of bowel cancer and can be given alone or with traditional chemotherapies. The drug is subsidised in Britain, France, Germany and the US for patients in this group. Cetuximab assists in shrinking tumours and slowing their growth by blocking the epidermal growth factor receptor, which promotes cell growth and division. Research shows that adding Cetuximab to pre-operative chemotherapy led to a 70% response rate in patients with KRAS wild-type tumours, with 34% of previously inoperable patients undergoing successful removal of all tumour tissue holding a modest prospect of cure. Cetuximab also improved the survival of patients with KRAS wild-type tumours who had failed all other standard chemotherapy treatments. Randomised phase III trials have demonstrated that Cetuximab can prolong the life of a late stage colorectal patient by an average of five months. [3.]

  2) Mutations affecting the KRAS gene are frequently found in tumours and studies show the KRAS gene status (wild-type v mutant) of bowel cancer patients is often useful for predicting the effectiveness of certain therapies and as a result, is internationally becoming the standard of care. Steps are being taken to make KRAS testing a standard part of the diagnostic procedure for advanced bowel cancer. In 2009, the National Comprehensive Cancer Network (NCCN) recommended that all patients with advanced bowel cancer be KRAS tested at diagnosis and the European Medicines Agency indicated that erbitux should be used exclusively in advanced bowel cancer patients with the KRAS wild-type gene (up to 65% of the patient population). [4.]

- Many patients have indicated their willingness to pay for the KRAS test (approximately $100-250 per patient) and Merck Serono have committed to continue to pay for the test in the interim if the Government will publically commit to funding cetuximab on the PBS for bowel cancer patients. We

recommend that urgent consideration be given to placing cetuximab on the PBS with/without the Medicare test rebate price being established.

(c) Any impacts on the future availability of medicines in the Australian market due to such deferrals; MOGA is concerned by the lengthening and increasing number of delays occurring within the Australian regulatory and government sectors with regard to the approval, subsidisation and access to oncology drugs or treatments. Above all, those that are widely available in comparable countries, in the pipeline and soon to be available internationally, that will have limited access to the Australian population. These delays are negatively impacting on cancer patients (in terms of their overall survival, emotional well being and quality of life) and their families as well as the level of support and assistance that clinicians can provide. While these delays are due in part to cost saving exercises, structural inefficiencies in the current, national process for oncology drug and treatment approval, subsidisation and access as well as the failure to develop a proactive national system for oncology drug treatment approval and access, are also part of the problem.

(d) The criteria and advice used to determine medicines to be deferred; The Association is not aware of the criteria and advice that was used to make the determination that the medicines be deferred. It is concerning that this information has not been made public with no regard for transparency considerations.

(e) The consultation process prior to a deferral: The Association is not aware of any consultation process that was implemented prior to the recent Cabinet deferrals. It is concerning that no consultation or regard for transparency considerations have been implemented.

Other related matters

Off Patent and Generic Oncology Drugs Issues: A number of oncology drugs are or are about to be off-patent and/or are available as generics but, used in current clinical practice and have proven efficacy in phase III trials, however formal submissions to the PBAC and PBS will never be made by the owning companies: eg., gemcitabine (Gemzar) and oxaliplatin, used in billiary and gastro-oesophageal cancers available respectively through State limited access programs. A national application process needs to be developed to allow professional organisations representing clinicians to make no-cost applications for the listing of drugs for other indications based on recent phase III trials or small trials for very rare tumours, in instances where there are no incentives for generic and originator pharmaceutical companies. These drugs issues relate to other speciality disciplines and represent a Governmental and Regulator policy void. PBAC and DOHA have been advising Government on these issues and have requested that MOGA submit a prioritised listing of oncology drugs for special consideration. MOGA would like to see debate around these issues that extends to the identification of legislative changes, barriers and consumer issues such as safety concerns. It is recommended that a Government system be established to support listing changes and to set the standard of data required and that the PBS introduce a no-cost facility for the submission of speciality clinician/group led oncology drugs and treatment submissions based on public interest values.

Information on the approval and listing of drugs on the PBS There is a need for all stakeholders to be better informed about the role and determinations of the PBS. It is recommended that the PBS put in place a communications strategy with targeted, high quality communications mechanisms to assist Australian stakeholders to understand its role and determinations: consultation and decision making processes: management and assessment cycles. Stakeholder engagement in the process of drafting the specialised communications materials would assist in more effective communications and advice, above all to medical practitioners.

Future Professional Consultation: It is recommended that the inquiry Panel consider developing a discussion paper based on the submissions received that can be circulated for comment and followed by targeted consultations with key stakeholder organisations, including MOGA. In particular, we would like to invite the inquiry Panel to seek our assistance on any relevant matters, or submissions that may require expert oncology and clinical advice of international best practice standard. It is recommended that this could include official representation to give evidence at the proposed Senate Committee hearings to be held at locations to be determined; PBS officially consult with specialist medical practitioner stakeholder group such as MOGA on an ongoing basis.

MOGA is currently developing a list of oncology drugs to be considered for special access by Government and a submission for the establishment of an Oncology Drugs Scheme to parallel the Palliative Care Clinical Support Model. In August the PBAC invited MOGA to submit information on oncology drugs that are in regular clinical application and/or where there is emerging or available trial data, but where there is no registered listing and

indication. This approach can serve as an example where the profession can assist the PBS in addressing a clinical need. Greater involvement of the professions in decision making would also assist in transparency and clinical relevance of decision making. It is essential for medical practitioners to have not only effective and efficient access to clinically accurate, up to date, timely, well-researched information but access as well as approvals for oncology drugs and treatments. Rapid changes and developments in medical research, clinical trials and clinical practice are not addressed by the current Australian drug approval and access process.

MOGA has substantial expertise regarding oncology drugs and treatments, and have been highly proactive in working closely with the Pharmaceutical Industry, DOHA, PBAC and Medicines Australia as well as the PBS and other stakeholder organisations on these issues. In 2005 MOGA formalised this process through an Annual Drugs Roundtable Meeting that gathers these parties together to consider emergent oncology drugs, treatments and related regulatory issues. This has proven to be a valuable and profitable forum for all parties, resulting in some significant changes to benefit the Australian health system. As the next stage in this process MOGA plans to establish a National Australian Cancer Clinical Advisory Group to work with the Australian regulatory organisations and Government. This Group would be the appropriate body to officially and formally liaise with the PBS with regards specialist, clinical and oncology advice, selected oncology drug and treatment submissions or issues.

In conclusion MOGA recommends;

- The Cabinet decisions in relation to the deferred drugs and treatments be rescinded due to their negative impact on patients and clinical practice, the lack of consultation with stakeholders, and failure to observe the extant, proven national pharmaceutical assessment and approval system.
- The implementation of a parallel assessment and approval process of biomarker testing for all oncology drugs and treatments regardless of biomarker status.
- Establishing a national expert Working Group representing all relevant disciplines to develop a detailed set of national guidelines and guiding principles for the implementation of high-quality oncology drug and treatment approval, subsidisation and access in Australia: including determining recommendations on emerging new drugs, treatments and related technical issues as well as associated translational research issues for national cancer care.

These recommendations would assist in ensuring that Australian medical, laboratory and research facilities, researchers, clinical practitioners and regulatory and governmental agencies can work co-operatively and in parallel to maintain the highest possible standards of patient care, at best practice, international standards. A co-operative approach will be required above all given the fact that a national and, possibly a global approach to the adoption of emergent oncology drugs and treatments will be required and will necessitate structural, management and operational changes across a number of sectors and jurisdictions.

MOGA would be pleased to assist further with facilitating the national process for oncology drug and treatment approval, subsidy and access and provide more detailed advice on any specific issues. In particular, MOGA would be pleased to assist in the development of the national guidelines and recommendations for a proactive, dynamic and leading edge clinical practice and research driven national approach and the provision of ongoing expert advice.

Our patients deserve and demand the right to timely access to oncology drugs and therapies that will provide them with the best opportunity to prolong their survival in good health. There can be no less for the Australian population. On behalf of the Association I would appreciate your earliest advice on the matters detailed herein. We look forward to working with the Government in 2011 on projects to benefit Australian clinical oncology practice and of the greatest importance patient care. We trust that the recommendations in this submission will be of assistance and would be pleased to provide further advice. We look forward to the inquiry's findings.

Yours sincerely,

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MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED
The Medical Oncology Group of Australia (MOGA) is the peak representative body for medical oncologists and the medical oncology profession in Australia. The Association works closely with Government, regulatory agencies, health organisations, affiliated international associations and societies, industry, consumer advocacy groups and learned colleges throughout Australia to improve and develop the profession of medical oncology and the management of cancer nationwide. The Association is a Speciality Adult Medicine.

1. http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-mtg-november-2010: Simpson K., et al. (2008 Dec). Fixed-ratio combination oxycodone/naloxone compared with oxycodone alone for the relief of opioid-induced constipation in moderate-to-severe noncancer pain. Current Medical Research Opinions 24 (12): 3503–3512: Mundipharma (2009 Jan). Targin (oral oxycodone/naloxone prolonged-release tablet) now launching across Europe to control severe chronic pain with significantly reduced risk of opioid-induced constipation http://www.prnewswire.com/mnr/targin/36704/.
2. Merck Serono (2011 Jan) Erbitux Product Information: Van Cutsem E., et al, Cetuximab and Chemotherapy as Initial Treatment for Metastatic Colorectal Cancer, New England Journal of Medicine 2009; 360:1408-17.

3. Folprecht G., et al, Neoadjuvant treatment of unresectable colorectal liver metastases: correlation between tumour response and resection rates, Annals of Oncology 2005:16 (8) :1311-1319; Ciardello F., et al, Awareness and penetration of KRAS mutation testing in the treatment of patients with metastatic colorectal cancer, ASCO Annual Meeting 2010 Abstract No e14074.

4. Ciardello F., et al, ASCO Annual Meeting 2010 Abstract No e14074 : NBBN Clinical Practice Guidelines in Oncology, Colon Cancer v2.2009: Merck Serono (2011 Jan) Erbitux Product Information: Van Cutsem E., et al, New England Journal of Medicine 2009; 360:1408-17.