MELANOMA PATIENTS AUSTRALIA SUBMISSION

ACCESS TO CANCER MEDICINES IN AUSTRALIA REPORT

The following submission is drafted by Melanoma Patients Australia (“MPA”) in response to the *Access to Cancer Medicines in Australia* report (“the Report”) released by the Medicines Australia Oncology Industry Taskforce.

Background of Melanoma Patients Australia (MPA)

MPA is the only patient driven non profit organisation in Australia that offers a national network of support and information to patients, their families, carers, and friends, about melanoma prevention, diagnosis, management and treatment.

MPA was founded by two young melanoma patients, Brent Grace (now deceased) and Daniel Belcher, and was officially launched on 6 July 2006 by then Governor of Queensland, Her Excellency Quentin Bryce AC, now Governor-General of Australia. Melanoma Patients Australia continues to grow in strength and numbers and is now one of the largest melanoma patient advocacy groups in Australia.

All of the services offered by MPA to patients are offered at no cost and are freely accessible by melanoma patients, their carers, family and friends. It is vital that all melanoma patients are given the best available support and care and it is for this reason we rely on the support of financial sponsors, donors and contributors to ensure our continued operation.

Vision

To reduce the impact of melanoma on all Australians.

Mission

Provide information, support, awareness and advocacy to people affected by melanoma and become the national peak body representing the interests of melanoma patients in Australia.

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Melanoma in Australia: Key Drivers

- Australia has the highest incidence of melanoma in the world - of the 12,510 Australians diagnosed with melanoma each year, about 1,450 will die from melanoma, and thousands of others experience recurrences or the detection of more primaries that in some cases eventually lead to death.[1]

- Melanoma is also a 'young person's' cancer - i.e. the most common cancer in Australian men and women under 45 years of age (however the incidence is highest in males over 60 years).[2]

- As the Report highlights, the incidence of melanoma in Australia is projected to increase between 2011 and 2020 by over 8 new cases per 100,000 population from 65.5 cases to 74.1 cases in 2020.[3]

- It is medically accepted that the best treatment for melanoma is prevention and early detection - up to 90% of melanomas can be cured with surgical removal of the melanoma and some of the surrounding normal skin.[4]

- Currently, there is no cure for advanced melanoma and the prognosis for patients who are diagnosed with melanoma at a late stage is limited. Unfortunately as the Report notes, there has been a 10% increase in the mortality rate for melanoma in Australia.[5]

Treatment of Advanced Melanoma

There is currently a dramatic shift in the treatment of advanced melanoma underway with a vast number of clinical trials being explored.[6] This changing treatment landscape is particularly exciting for patients given the treatment of melanoma was standard for nearly 40 years with minimal improvements. Current clinical trials are offering hope to patients with advanced and metastatic melanoma as they examine new therapies, particularly new biological and targeted therapies, including those used in combination.

New treatments offer improved life expectancy to advanced melanoma patients although only one treatment is currently funded through the PBS - Ipilimumbab (also known as Yervoy) was listed as at 1 August 2013. Prior to the PBS listing of Yervoy, there were many Australian melanoma patients who were forced to pay full price for access to the treatment (approximately $120,000.00) which placed the treatment outside the reach of many terminally ill patients.

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[1] See Chart 2.1 of the Report (refers to AIHW (2012b) data).

[2] AIHW (2012).

[3] Charts 2.8 and 2.9 of the Report.

[4] Melanoma Patients Australia website and resources.

[5] The Report, p14 (referring to AIHW (2012b)).

[6] As noted in Chart 3.2 of the Report, there are 16 phase 2 and 3 clinical trials for melanoma currently underway globally.

Despite the many strides being made in the research into treatment for melanoma, this does not always guarantee improved outcomes for melanoma patients in Australia. For example, the manufacturers of Vemuafenib (Zelboraf) chose to withdraw the treatment from the PBS process following two unsuccessful reviews and a failure to reach agreement with the Government regarding the cost. The manufacturer also ceased compassionate access to the treatment given the uncertainty relating to the future commercial viability of the treatment in Australia through listing on the PBS. The impact of this situation on patients was significant, as Australian melanoma patients were denied affordable, equitable access to a new advanced melanoma treatment that has been approved by the US Food and Drug Administration in August 2011 and further by the Therapeutic Goods Administration (TGA) in May 2012. Australian melanoma patients currently seeking to access Zelboraf are only able to do so by paying for the treatment privately and at great personal expense.

Impact on Melanoma Patients in Australia

There is great anticipation and excitement amongst the melanoma patient community in Australia as recent therapies are showing great promise and trials of personalised medicines are indicating improved treatment outcomes. Ideally, melanoma patients seek fair and equitable access to affordable treatment options in their lifetime and while the treatment can offer some benefit. It is difficult for patients to understand the delays in gaining access to treatment and having to wait when there prognosis indicates they only have a short time to live.

While a drug is in the clinical trial phase, it can be difficult for a melanoma patient to access it even though it may potentially be beneficial for reasons such as the strict selection criteria of the trial, for example the existence of other co-morbidities, the location of metastases (particularly metastes in the brain) and previous treatment already received for the melanoma. There is scope for improvement in this regard by a thorough review being undertaken by the manufacturers and/or researchers to develop a broader selection criteria for clinical trials that might enable greater patient involvement. Further the geographical location of clinical trials can be prohibitive (some patients are unwilling or unable to travel from remote regions to metropolitan centres to participate in trials) and some patients fail to gain access to clinical trials through their primary care provider (due to lack of knowledge of or experience with enrolling patient/s in melanoma specific trials).

Equally, it is not a sustainable or reliable model for melanoma patients in Australia to be dependent on the lobbying efforts of their treating clinician to gain them access to a clinical trial or compassionate access to a treatment with a pharmaceutical company, particularly in circumstances where this is the only hope of improving the outcome for the patient, even if only for a short period. It imperative that treatments that are safe and TGA/FDA approved be made available as soon as possible as a standard treatment option on the PBS. Advanced melanoma patients are dying while the PBS listing process of the current best treatments for advanced melanoma is undertaken. Any opportunity for review of the current laboursome and time consuming PBS Listing process is welcomed by MPA on behalf of Australian melanoma patients as the obvious benefits to patients are clear. It is not suggested that any review that would hasten the process of PBS Listing compromise due diligence, accountability or overall patient safety. Rather, there are some aspects of the PBS Listing process as identified by the Report that could occur in a concurrent and/or streamlined manner.

Melanoma patients in Australia seek confidence in knowing that the treatment options available to them are current best practice and are not restricted due to bureaucracy and administrative delays. It is not good enough from the patient's perspective that there are viable treatments for advanced melanoma available globally that have received TGA and FDA approval (eg Zelboraf) that cannot be accessed by patients in Australia. The PBS Listing process must be reviewed to enable the listing of new treatments to be undertaken in a timely and efficient manner for the benefit of patients who are waiting for access to the potentially life extending treatments. Unfortunately many advanced melanoma patients do not have time to wait for the PBS process to be finalised and the cost of private access to treatments can be prohibitive.

As the various trials proceed and the efficacy of new melanoma treatments is identified, it is vitally important for melanoma patients to have prompt and reliable access within Australia. The current protracted system is forcing many patients to consider experimental treatment options available in regions outside of their immediate community (particularly in the instance of melanoma patients in more regional areas) and/or overseas. In some instances, MPA is aware of patients and their families travelling abroad to Mexico, Germany and the United States of America to access treatments at significant expense and personal cost. Obviously this is not a sustainable situation for melanoma patients, particularly when in late stages, and ideally the system of approving treatment availability in Australia must be reviewed as a matter of priority.

Through the MPA patient network we are aware of melanoma patients hosting fundraising events to pay for their own treatment; other patients contemplating selling their family home and still others looking to access their superannuation, in order to fund their treatment costs. It is unacceptable for critically ill melanoma patients to be seeking to subsidise the cost of their own potentially life saving treatment in this manner. Many advanced melanoma patients do not have the physical ability (largely due to their symptoms), experience, network or nouse to undertake the mammoth task of seeking public support for funding. Such fundraising and publicity efforts take time which many patients simply do not have the benefit of. Melanoma patients are being asked to gamble with their own financial security and rely on the support of their communities to fund treatments that should be PBS Listed.

The current model of patients achieving timely, affordable and equitable access to best treatments for advanced melanoma is flawed. The experience in the melanoma community of the withdrawal of Zelboraf from the PBS process only highlighted the precarious and frustrating position that melanoma patients are in. There are viable, effective and life extending treatments in existence in Australia but only if you can afford it; if you live near a research centre or are prepared to travel away from your place of residence; or if your disease progression and treatment to date bring you within the strict criteria applicable in the clinical trial setting. This is creating an uneven treatment setting for melanoma patients in Australia. As the incidence of melanoma in Australia continues to rise and the mortality rate increases, the issue of fair and equitable access to potentially life saving treatments should be paramount for the Australian government and more broadly the Australian community.

Melanoma is commonly termed “Australia’s Cancer” given we have the highest incidence in the world, and because of this, as a nation we should be leading the way. After all, what is the cost of an Australian life? By addressing the deficiencies in the PBS Listing process the treatment options for advanced melanoma patients will be improved; positive patient outcomes increased; and, a greater equality of access and affordability to melanoma treatments for all patients achieved. Australian melanoma patients seek to have a reliable clear treatment path available to them through the PBS inspiring in them hope of improved survival and confidence that the best care possible is available and is being provided to them right here in Australia.

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