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Submission To The Select Committee on Health

Prepared by the Cancer Drugs Alliance, September 2014

Executive Summary

Australia has the highest age-standardised incidence of cancer in the world. 1 in 2 Australians will develop cancer in their lifetime and 1 in 5 will die from cancer before the age of 85 years. Cancer kills 45,000 Australians each year accounting for 3 in 10 deaths. Australia is known for having the highest rate of prostate cancer and melanoma and the third highest rate of breast cancer in the world.

However, Australian cancer patients face significant delays and expense in accessing new cancer drugs, or worse they are missing out altogether. Cancer patients unfortunately do not have the luxury of time to wait months or in some cases years for the best medicines to become available; Australian patients need, expect and deserve timely and affordable access to available cancer medicines.

Experiences of other countries demonstrate that we can address the issues of timely and affordable access for patients now and in learning from other countries we have an opportunity to improve the outcomes of Australian cancer patients now.

The CDA recognises that achieving both timely and affordable access to new cancer medicines for the long-term will require a fundamental reform of the current system and that to investigate new ways of changing or modifying the system will take time, time that cancer patients sadly do not have. Therefore, while such reform takes place, Australia needs to implement an interim solution and the CDA wishes to work with Government, and other cancer stakeholders, to ensure that Australia delivers a world-class system for cancer patients.

The CDA welcomes the opportunity to provide this response to the Select Committee on Health. Australian patients can no longer afford to delay – we must act on their behalf and we must act quickly.

The Policy Issue

The Burden of Disease

Australia has the highest age-standardised incidence of cancer in the world. 1 in 2 Australians will develop cancer in their lifetime and 1 in 5 will die from cancer before the age of 85 years. Cancer kills 45,000 Australians each year accounting for 3 in 10 deaths.

In 2012, cancer was estimated to account for 551,300 disability adjusted life years (DALYs) in Australia; of these, 457,400 were years lost due to premature death and 93,900 were years of healthy life lost due to disease, disability or injury (*Australian Institute of Health and Welfare & Australasian Association of Cancer Registries 2012. Cancer in Australia: an overview, 2012. Cancer series no. 74. Cat. no. CAN 70. Canberra: AIHW*).

As the official 'cancer capital of the world' – with an estimated 128,000 new cancer cases to be diagnosed this year and half of all Australians predicted to develop cancer in their lifetime – no other country faces such a significant and urgent need to act and address this challenge for the long-term. By 2020 cancer cases will jump 40% - with an estimated 150,000 Australians receiving a diagnosis. Cancer patients unfortunately do not have the luxury of time to wait months or in some cases years for the best medicines to become available.

Cancer presents the highest disease related burden on society accounting for 19% of the total burden but despite this Australia continues to spend an alarmingly low proportion of its healthcare expenditure on cancer drugs, with only 6.4% of Pharmaceutical Benefits Scheme (PBS) expenditure attributed to cancer drugs. As a result Australian patients are either being denied potentially life-saving drugs that are available in other countries.

Access to Medicines

Globally there are more than 900 cancer medicines currently under development. Research published in 2013 indicated there are more than 250 indications across 114 chemical entities currently in Phase II and Phase III trials in oncology being conducted by 16 major pharmaceutical companies (*Deloitte Access Economics: Issues on access to cancer medicines in Australia, July 2013*).

Approximately 44 new applications are likely to be submitted to the PBS (PBAC) by the end of 2015. Timely and affordable access to cancer medicines is a problem now and is likely to become considerably worse in coming years. There continues to be significant investment in cancer research from public and private sectors throughout the world, including Australia. This has led to many dramatic advances in the way cancer is now treated. However the full potential of this fast paced research will only be realised if patients have timely access to drugs that are shown to be effective.

The PBS is currently the only means of providing Australian cancer patients with broad and equitable access to cancer medicines. While the PBS has served Australians well for over 60 years, it has not kept pace with technological advances in cancer treatment and clinical practice. As a result, the approval rate of new cancer drugs is low with more than 80% of first applications for new drugs being rejected. This means many Australian patients are waiting longer than patients in many other countries to access the same cancer medicine.

Australia’s medicines access process, via the Therapeutic Goods Administration (TGA) and the PBS, is no longer keeping pace with the rapid advances in development of cancer medicines, and historical approaches to determining ‘value’ mean that the system is failing patients and clinicians. According to research published in 2013, the average time between TGA approvals to PBS listing is now 31 months, up from 15 months over the past 10 years (*Deloitte Access Economics: Issues on access to cancer medicines in Australia, July 2013*).

While cancer patients and their families wait for cancer medicines to be approved by the PBS, they may face significant hardship, either financial and/or from the physical and mental burden of the cancer. Patients have few options other than to pay a significant amount of money out of their pocket for treatment while they wait.

In addition, this puts a significant limitation on a doctor’s ability to deliver the best possible care to Australian cancer patients. Cancer physicians often encounter the moral and ethical dilemma of raising the issue of cancer medicines with the patient as there may be a treatment available, but the patient may not be able to afford the treatment until it is reimbursed.

In the period of 2011-2012 nine pharmaceutical companies provided more than 4,700 Australian patients with compassionate access and more than two-thirds (67.9%) of supplies were to cover the access gap between TGA registration and PBS listing, with access mostly provided free of charge (85.2%).

Compassionate access or cost-sharing programs are helpful in the short-term for specific patients, but do not provide long-term, sustainable or equitable access as their intent is to provide short-term access while medicines are fully reviewed via the appropriate Government processes for reimbursement approval.

A Global Issue

This policy issue is not confined to Australia. It is a challenge facing many Governments around the world, particularly comparable countries in Europe and North America. Some countries have already taken action and, as a result, cancer patients in other countries have access to new cancer medicines that Australian patients are being denied. For example, in 2011, a Cancer Drugs Fund was established in England in order to provide a means by which cancer patients could equitably access the latest approved, safe and effective cancer drugs. A different mechanism called the pan-Canadian Oncology Drug Review has also been established in Canada to improve access to cancer drugs.

The English fund continues to cover approximately 30 cancer drugs and during the 4 years it has been in existence has allowed more than 55,000 cancer patients to receive treatment they would have not have otherwise had access to.

Where countries such as the UK have introduced reform, clear improvements in access to cancer medicines have been seen – both in terms of faster approval times, and more medicines being available.

An independent analysis commissioned this year, to compare Australia’s performance with similar countries Canada, France, Germany and the UK, found that on average, it takes more time to achieve access to a subsidised medicine in Australia than in the other countries (*Reimbursement success rates and timelines for new medicines for cancer; an international comparison; Michael Wonder; March 2014*). In Australia, new cancer medicines need to be submitted at least twice on average before being listed on the PBS, which can mean significant delays.

There are other policy options that have been adopted globally for addressing the financial challenges faced by patients. For example, patients in countries such as America are able to insure against the high cost of drugs ranging from full drug insurance (where the patient pays no out-of-pocket expenses) to co-payments for a set amount per prescription.

The CDA believes that in finding a solution for improving access and affordability for Australian cancer patients this Inquiry should also investigate the models in use elsewhere in the world and in learning from the advantages and disadvantages of each one, develop Australia’s own best-practice model.

A Growing Problem

Australian cancer patients wait longer than counterparts in other comparable countries for access to cancer medicines. An independent analysis commissioned this year found that the average time from TGA registration to PBS listing was almost 20 months for new listings, and more than 24 months for subsequent listings, with the maximum time taking more than 52 months (4 ½ years) and close to 80 months (6 ½ years) respectively (*Reimbursement success rates and timelines for new medicines for cancer; an international comparison; Michael Wonder; March 2014*).

Rapid scientific advances in global cancer research have shifted the treatment landscape towards targeted cancer therapies. These targeted medicines have brought more treatment options, improved patient quality of life and survival but have brought challenges to the regulatory and reimbursement processes. Local processes, introduced 20 years ago, have not evolved to reflect these rapid scientific advances. Regulatory and reimbursement approval processes therefore need to evolve now to meet this changing treatment environment.

In addition, many of the cancer treatments are 'end of life' therapies (defined as treatment administered to patients with a prognosis of 2 years or less). To date, there has been no meaningful debate in Australia about the 'value of life', including 'end of life care', and what the community considers acceptable. It is timely now for all involved in cancer care to consider these values and assess how best Australia should provide access to these important medicines.

Cancer medicines are simply an acute example of current challenges with medicines reimbursement via the PBS. There are many other medicines across different disease areas that face similar challenges in securing timely access for patients.

Conclusion

Resolving the issues of timely and affordable access to cancer medicines for Australian patients is now critical and requires a long-term solution to cancer drug funding that is fair, equitable and sustainable. Finding the solution requires us all to work together to examine the way cancer drugs are currently funded and to determine how we can all improve outcomes and reduce the delays in access for Australian patients.

Without significant long-term, sustainable reform, Australians will wait longer and longer to access to cancer medicines that are available elsewhere in the world. Where other countries have introduced reform, clear improvements to cancer medicines have been seen, both in terms of faster approval times and more medicines being available to patients.

About 100 cancer medicines are currently subsidised under the PBS, with about the same number again in late-stage development. This is good news for patients but means the system has to be able to manage access to those medicines effectively and equitably.

The CDA recognises that achieving both timely and affordable access to new cancer medicines for the long-term will require a fundamental reform of the current system and that to investigate new ways of changing or modifying the system will take time, time that cancer patients sadly do not have. Therefore, while such reform takes place, Australia needs to implement an interim solution and the Cancer Drugs Alliance wishes to work with Government, and other cancer stakeholders, to ensure that Australia delivers a world-class system for cancer patients.

Australia is in an ideal position to lead the world in developing a sustainable, equitable and fit-for-purpose cancer medicines access system. While other countries have developed their own approaches, such as the UK's Cancer Drugs Fund and Canada's pan-Canadian Oncology Drug Review, we do not believe either of these options, in isolation, offers the best solution for Australia. We need to take the learnings from these approaches and build the best elements into the Australian system. This is an opportunity for Australia to take a leadership role in this area, and develop world's best practice in cancer treatment.

The Cancer Drugs Alliance is now calling for a review of current funding processes and is seeking to work with decision-makers in Canberra to explore long-term and short-term, sustainable strategies to urgently address the crisis in the access to cancer medicines we are seeing in Australia.

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About the Cancer Drugs Alliance

The Cancer Drugs Alliance (CDA) is a not-for-profit multi-stakeholder organisation committed to improving timely and affordable access to cancer medicines and achieving the best outcomes for Australian cancer patients. Membership of the CDA is comprised of practising oncologists, haematologists, representatives from cancer patient support and advocacy groups, and pharmaceutical companies currently providing cancer treatments to the Australian community.

The CDA aims to draw much-needed attention to the serious issue of inequitable, unaffordable and delayed access to cancer medicines in Australia, which is seeing many Australian cancer patients denied access to, or paying great sums in out-of-pocket expenses for, new cancer medicines that are readily available in other countries.

The CDA does not advocate for any one cancer treatment, it seeks to improve access for all Australian cancer patients and believes that only by bringing together the expertise of those engaged in cancer care, treatment and support will Australia achieve the shared goal of delivering world's best practice in cancer care and treatment.

For more information about the CDA please see our website at: www.cancerdrugsalliance.org.au

Alternatively please contact the CDA via email: info@cancerdrugsalliance.org.au