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cancer voices australia

Senate Community Affairs References Committee Inquiry
The availability of new, innovative and specialist cancer drugs in Australia

Submission by Cancer Voices Australia

Background to the issue and place of cancer in Australia
Cancer Voices Australia thanks the Senate Community Affairs References Committee for initiating this Inquiry. The issue it addresses is one which has been growing in importance to the community generally, but especially for the many Australians affected by cancer – 128,000 new diagnoses (AIHW) in 2014 and growing with our aging population and earlier diagnoses. It is projected that there will be 150,000 cancer diagnoses in 2020.

Cancer is a big-picture disease for Australia, in its death rate and health burden. Cancer is now the greatest cause of Australian deaths at 43,000 in 2010 (AIHW), having recently overtaken heart disease. It is accepted that cancer presents the highest disease burden on our society. Sheer numbers and the frequent urgency of this disease mean that the demand for new cancer drugs will continue to rise.

The relative uncertainties in understanding and treating cancer mean that most cancers demand an ever-increasing arsenal of new drugs to attempt limited prevention, "cures" of the disease and/or its recurrence, or to establish holding patterns (of disease progression and quality of life). While major advances have been made in recent years leading to longer life expectancy through more-targeted and more tolerable drugs, and even to chronicity, the problem of how best to treat cancer remains a major challenge.

This is the general background in which the pharmaceutical industry operates in bringing new cancer drugs to the market. Most new drugs are expensive to develop and to market. They may appear to offer only marginal improvements in the population on which they are trialed, although frequently they prove to be more effective in the real patient population. This can only be properly evidenced when we have a better process for post- marketing surveillance and real data linkage.

Cancer Voices Australia has been concerned about all aspects of this Inquiry's Terms of Reference for many years. A Position Statement on *Access to High Cost Dancer Drugs* was posted on our website in April 2014 and is attached to this Submission. Last year CVA joined the tripartite Cancer Drugs Alliance to provide, along with other cancer-specific consumer groups, the informed consumer view in the Alliance's concerted push to gain attention to this issue. CVA participated in the design of a CDA-commissioned survey of its consumer groups' views about what needs to be changed (Stakeholder Perceptions Study, GA Research Nov 2014), and we commend its report to the Inquiry.

Other countries have recognised the same conundrum and have developed various "special track" models to address it, either in the short term (UK's Cancer Drugs Fund established in 2011) or the longer term (Pan-Canadian Oncology Drug Review). Australia is not alone in facing this major and growing future problem for people diagnosed with cancer, and we may well be able to learn from the successes and failures in other jurisdictions.

Summary recommendations

We need a better, quicker and more affordable way for Australians diagnosed with cancer to get the drugs they need. Many of us can't wait for the years that our present approval process takes, nor can we afford to pay the full unsubsidised costs.

Cancer Voices Australia asks the Inquiry to recommend that Government looks at the availability of new, innovative and specialist cancer drugs in Australia as a *special case*, to be approached differently to the general process for subsidy on the Pharmaceutical Benefits Scheme. We believe that the argument, based on the different scenario posed by the nature of our disease and its treatment, is sufficiently strong to warrant this. This principle should also be applied to the Medical Services Advisory Committee's (MSAC) processes for cancer-related items as well, as a number of new cancer drugs are co-dependent on new tests which enable targeting of drugs.

Cancer Voices' seven specific recommendations

- **We call for a faster process to get Australians onto the cancer drugs which will help them, possibly using a special fast-track process.**
- **We need to be able to assess cancer drugs' effectiveness and impact on quality of life in real-life use (ie not just in clinical trials) using post-marketing surveillance**
- **We need an agency or registry to collect and link data about real-life benefits and side effects**
- **We should closely examine cancer specific drug access solutions reached in other countries to see which elements could work in Australia**
- **We should consider using accredited overseas approvals under certain conditions to enable faster access to new cancer drugs**
- **We should examine the case for a public interest facility which could sponsor drugs and technologies which are not of interest to industry**
- **We recommend more effective and timely consumer input within the PBAC and MSAC processes**

Comment on the Inquiry's Terms of Reference.

a. The timing and affordability of access for patients

Due to the nature of their disease, many cancer patients commonly cannot afford to wait long periods to access new drugs, or even old ones which have been found to work with other cancers, but are not yet approved for that purpose.

Case study re timing: A Cancer Voices member has advised that the next cancer drug for her specific subset of advanced ovarian cancer (she has the BrCa mutation) was not expected to get through the approval for subsidy processes until 2018. She is asymptomatic and productive now, but without the next advance for her situation, will deteriorate – and well before the expected three-year wait is over. This situation is exacerbated by the fact that there are few people in her cancer subset, so potential pharma sponsors may not be willing to invest in the approval processes. Worse is the knowledge that that the new drug has recently been approved in other reputable western jurisdictions (in USA and in Europe) but not by our Pharmaceutical Benefits Advisory Committee (PBAC), let alone been placed on the Pharmaceutical Benefits Scheme (PBS). It is plain that there is something wrong in a system like this which cannot take advantage of the accredited approval systems of similarly-reputable health systems and populations to reduce the delays in the approvals process for Australians.

Affordability is another barrier to access. The cost of a new cancer drug which has not yet become available on the PBS can have a major negative impact on a cancer patient and their family. Either they will forgo suing the drug, or generate anxiety and financial distress (sometimes referred to as "financial toxicity") by meeting the $50,000 - $150,000 per annum pharma charge. Often this is on top of having had to leave the paid workforce.

It should be recognised that there are several routes to access cancer drugs which have not yet achieved listing on the PBS - routes for which there is no cost or little cost. These include:

- The *Special Access Schemes* (via the Therapeutic Goods Administration (TGA) applies to drugs which have not yet been registered for the approval process and provide a means of access for some cancer patients, usually at end-of-life situations.
- *Expanded or Compassionate Access* is often offered by pharma companies who expect PBAC drug approval soon. These programs are extremely helpful in addressing timely access and affordability, but the criteria (eg sequence and type of previous drugs prescribed) are often quite rigid. Such access is usually free to patients, or may be offered on a cost-sharing basis.
- A *Clinical Trial* may be another option for some cancer patients who meet specific criteria. In such cases, the drug is usually free, but if the trial is randomised, there is no certainty that the patient will receive the new drug.

Skewing of demand and supply through availability and cost factors may well lead to oncologists and their patients looking for other ways of accessing the drug supplies they need – eg via the internet. Our approvals system is designed to protect us from unregulated drugs, but may end up forcing us to take such routes in sheer desperation.

"Luck-of-the-draw" timing impact: Due to delays in the approval process, a family may sell its house and jettison collective family savings to access a drug that has become 'legendary' through overseas experience of apparently successful outcomes. A few months later that same drug has likelihood of becoming free on the PBS to other cancer patients. By a twist of fate in timing, one patient's family is bankrupted and another has free access. "Evidence-based" access is not the principle here – it is 'luck-of-the-draw' with timing.

b. The operation of the Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefits Scheme in relation to such drugs, including the impact of delays in the approvals process for Australian patients:

The aim of the PBS is to ensure Australian patients have broad and equitable access to cancer drugs. The process has served us well over 60 years and is regarded as a world-class process for delivering subsidised drugs and for "reimbursing" the pharmaceutical industry. However it has not kept up with technological advances in cancer treatment and clinical practice. Tests are increasingly becoming part of decisions about which cancer drugs will be effective for individual patients. Patients needing these face similar or longer delays within the MSAC process. The Cancer Drugs Alliance (CDA's Select Committee on Health Submission, Sept 2014) notes *"As a result, the approval rate of new cancer drugs is low, with more that 80% of first applications for new drugs being rejected. This means many Australian cancer patients are waiting longer than patients in many other countries to access the same cancer medicine".*

Targeted cancer therapies have brought more treatment options and improvements to our quality of life and to survival, but are now challenging the ability of the present regulatory and subsidy / reimbursement processes to be fit for purpose.

Life-Saving Drugs Program (LSDP): The laudable LSDP offers subsidised access for eligible patients to life-saving drugs for rare, life-threatening conditions. However problems arise for cancer patients with less common or rare cancers due to definitions, the required level of data and TGA regulatory requirements – all basically due to small patient numbers. Cancer Voices understands that a Review of this Program is currently under way and recommends its findings to this Inquiry.

Limited opportunities for consumers and consumer groups to have input into PBAC and MSAC processes: This is a long-standing bone of contention for many Australian health consumer organisations. Best practice consumer engagement requires there be two consumers on decision-making committees, for a range of reasons. This is particularly relevant for the PBAC and MSAC processes. These representatives of consumers need some assistance, especially when making decisions about diseases and conditions with which they are unfamiliar. The existing consumer input processes allow little time and present a number of problems for valuable consumer input – see examples below.

Opportunities for consumer input was the subject of the GA Research Report for the Cancer Drugs Alliance (CDA, Nov 2014). Consumer group participants in a CDA Stakeholder Forum held in March 2014 were later surveyed about the principal aspects of the PBAC process that should be changed in their view. We believe that the same views would apply to the MSAC process. Key findings were:

- More focus on the quality of life for individuals – less on cost-effectiveness
- More visibility and transparency of the drug approval process
- Improvements to the PBAC submission process to enhance consumer input
- Greater consumer involvement in this process, including more than one PBAC panel seeking advice from consumers or a specialist cancer consumer panel
- PBAC process to be updated to keep pace with medical and technological advancements

Cancer Voices South Australia reports on some of the difficulties faced by consumer groups trying to contribute to the PBAC process: "*We have people who want access to the drugs being reviewed, but we have enormous difficulty finding the people PBAC really want to hear from ie people who have used the drug and have their experience to report. These people are either well, and not aware the drug is up for review, or very unwell and moved on to another treatment or to palliative care. Either way, it is very difficult for us to track them down and get their informed feedback. They have usually received the new drug via clinical trials or other Special Access program. Only their clinicians or the hospital's oncology pharmacy department know who these people are, and are unlikely to be supporting them to contribute to a PBAC review".*

A Cancer Voices South Australia member also comments: "*As to whether cancer consumers are well integrated in the process, this appears poor with few submissions made for input despite the apparent willingness of the PBAC to receive views. I'm not even sure how the views of consumers can add to the listed terms of reference of the committee - a problem in itself. Looking at the most recent agendas, cancer treatments seem to make up the greatest number of submissions with probably 20% of all listed, and yet the sole PBAC consumer member does not have a cancer experience background. The online process is not the easiest with no dates for the four 2015 meetings yet published and no way of setting up a RSS reminder/alert or similar to engage consumers. From a practical perspective perhaps this can be improved with a more formal input process, requirements for adequate consumer input/comment and greater effort on ensuring comment, perhaps supporting the PBAC consumer member with resources to*

advocate on consumers' behalf. There are sub committees for economics and drug utilisation, why not a patient or community impact panel?

This does all seem almost too late in the process. Submissions made by pharmaceutical companies are based on economics and new cancer drugs available overseas are not being released into this country due to lack of sponsors willing to pay in a small population. In many cases this is not about new drugs but about new uses for old drugs e.g. breast cancer drugs now being trialed for sarcoma. So perhaps they should look at providing support for public interest submissions put up by Cancer Australia or an NGO? "

c. The impact on the quality of care available to cancer patients

Cancer Voices recognises two impact areas here, on both *quality of care* and, just as importantly, *quality of life.*

Impact on quality of care: The quality of cancer care is negatively impacted when the most appropriate drugs for a particular patient's cancer profile are not available in Australia and/or are not subsidised via the PBS. Some patients' clinicians are reluctant to even mention that a drug is available, though unsubsidised, if they believe the patient and family are unable to pay the price of $50,000 - $150,000 per year set by pharma companies.

A related problem is that some tests which show whether a specific drug regime is having a positive effect are not subsidised by Medicare – because they are not approved by MSAC. An outstanding example of this is Positron Emission Tomography (PET). These scans have the ability to show cancer activity, spread and aggressiveness within the body. PET is subsidised via Medicare for some cancers, but not all – including advanced breast cancer. I am myself in the position of taking a PBS taxpayer-funded drug costing $70,000 per annum, but must find the $600 for a PET scan every few months to ascertain if the drug is being effective. I am able to afford this, but many are not. This situation strikes us as being a clear example of false economy. If my PET scan shows disease progression, I will stop taking that very expensive drug and not waste public money. I will also have a good idea about what my cancer is doing, which will inform my choice of possible next options. Technology that supports best-practice cancer care needs to be available to everyone who will benefit from it and PET scans should be covered by Medicare wherever they are effective in monitoring disease progression and its response to cancer treatment.

Impact on quality of life: Some cancer drugs aim to be curative; others seek to deliver a better quality of life and/or longer life. Cancer is becoming more like a chronic rather than terminal disease for many, but as such generates an increased focus on quality of life. Cancer Voices is concerned that quality of life may not be adequately weighted when approval decisions are made by the PBAC. This is a compelling reason for greater input from consumer organisations when PBAC is making approval decisions, especially as Australia has little post-marketing surveillance of disease- control effectiveness or the maintenance of good quality of life. We recommend that cancer consumer groups, such as Cancer Voices and the Australian Cancer Consumer Network (a new network of 30 cancer consumer groups), be consulted to obtain the broad view of the many. Non-networked individual consumers are usually less well-informed about the cancer community's wider experience of impacts on the quality of life.

It is time that the concerned community had a meaningful debate about the value of life, including its quality, and indeed the "end stage", so that we can agree what is acceptable.

d. Any related matters

The conundrum for pharma companies

Pharma companies point out that research & development (R & D) costs to develop a new drug for use by 10,000 people are the same as the cost of developing one for 1,000,000 people. New cancer drugs are becoming more targeted for specific populations and their cancer profiles, which obviously reduces the potential market size in each case. The problem is even greater for "orphan cancers" (those categorised as less common or rare) whose market size is small regardless of subset profiles. Another issue is that while R & D costs are immediate, health benefits often don't accrue for years. Combine this with the patent expiry regime, which dictates that costs must be maximised via a monopoly status while the patent is in force, because a drug's market price will tumble when its intellectual property becomes accessible to competitors.

We acknowledge another view as expressed by the New York Times (31 Jan 2015): *"Of course, pharmaceutical companies claim they need to charge high prices to fund their research and development. This just isn't so. For one thing, drug companies spend more on marketing and advertising than on new ideas. Overly restrictive intellectual property rights actually slow new discoveries, by making it more difficult for scientists to build on the research of others and by choking off the exchange of ideas that is critical to innovation. As it is, most of the important innovations come out of our universities and research centers, like the National Institutes of Health, funded by government and foundations."*

Cancer Voices recommends that decision-makers recognise the position faced by pharma as well as consumers' need to access new cancer drugs in good time and at affordable cost. We should examine the case for a public interest facility which could sponsor drugs and technologies which are not of commercial interest to industry.

Discussion

Can drivers and regulations be altered to find a way which better serves cancer consumers, regulators, government, and the community? That is the big question for this Inquiry.

While we call for refinement of the PBAC process, perhaps by the introduction of a special "track" for new cancer drugs, we should be aware of some other barriers. There has been considerable discussion about how to change the research / clinical trials process, especially in the case of targeted cancer therapies for smaller groups of patients. We would like to see the NHMRC and regulatory agencies take a lead in this area by accepting and encouraging the adoption of changes – recognising that one size for clinical trial requirements does not fit all research. We do not of course want to see any adverse impact on rigour or safety.

Our ethics approval system may also provide a barrier at times. Its rather arcane requirements can delay necessary research - sometimes by years. Recruitment is often hampered by the numbers of ethics committees through which approval is sought in multi-site trials. The process may also require adjustments to reflect the changes in technology and science that are upon us, especially in the area of new cancer drugs. Cancer consumers *per se* are excluded from the considerations of ethics committees, which means there is no input based on relevant consumer experience. This could be a case for cancer specific ethics committee, as established in NSW by the Cancer Institute NSW, but for unknown reasons, disbanded.

Cancer Voices supports the call for an interim solution, such as a special track for cancer drugs, to be considered by the Inquiry. This would provide some time – a commodity that is very limited for many of us - for the present processes to be brought up to speed and aligned with the changed nature of the science, the direction of cancer drug development and the need for more effective consumer input.

About Cancer Voices Australia

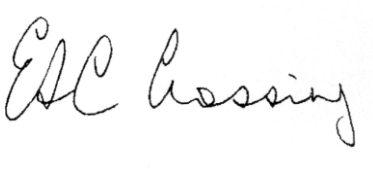
Cancer Voices Australia (CVA) is the independent, 100% volunteer voice of people affected by cancer, working to improve the cancer experience for Australians, their families and friends. CVA is active in the areas around diagnosis, information, treatment, research, support, care, survivorship and policy. To achieve this, CVA works with decision-makers, ensuring the patient perspective is heard.

Cancer is now the greatest cause of deaths, and Australia's biggest health burden. People affected by cancer know there is much scope for making a real difference through acceptance of their voice as an integral part of decision-making.

Cancer Voices has led the cancer consumer movement in Australia since 2000. Cancer Voices facilitates the Australian Cancer Consumer Network (ACCN), which brings together 30 organisations concerned about cancer consumers, achieving a louder, informed national voice on issues of mutual interest. CVA has encouraged ACCN groups to make their own submissions to the Inquiry and we understand that a good number have done so.

Cancer Voices thanks the Senate Committee for this opportunity to contribute to the discussion about possible solutions that will improve the availability of new, innovative and specialist cancer drugs in Australia.

Yours sincerely



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