Submission to the Senate Community Affairs References Committee Inquiry into the

Availability of new, innovative and specialist cancer drugs in Australia

February 2015
Consumers Health Forum of Australia

Introduction
The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

This submission into the Availability of new, innovative and specialist cancer drugs in Australia draws on the experiences of our members and consumer representatives in assessing the availability and effectiveness of medicines in Australia, and in particular the operation of the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Scheme (PBS).

This submission mainly addresses the inquiry’s second term of reference, “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 approval process for Australian patients.” However, we also endorse the submission from Cancer Voices Australia (CVA), who is one of our member organisations, which responds to all the terms of reference and is developed through strong link to the lived experience of people with cancer.

In particular we would draw your attention to CVA’s recommendations that the Federal Government:

- Implement more effective and timely consumer input within the PBAC and MSAC processes.
- Be better able to assess cancer drugs’ effectiveness and impact on quality of life in real-life use (not just in clinical trials) using post marketing surveillance.
- Closely examine cancer specific drug access solutions reached in other countries to see which elements could work in Australia.

While we have drawn our submission primarily from consultations with CHF members and our experience in PBAC and PBS issues, we would like to emphasise that this inquiry cannot be considered in isolation from other, ongoing Federal Government reviews. These include the Minister’s recent consultations on the future of the PBS, the Review of Medicines and Medical Devices Regulation and the Review of Life Saving Drugs Programme. The outcomes of these reviews are likely to have significant impacts on consumers’ access to new, innovative and specialist cancer drugs and the Committee ought to be cognisant of them in forming its final recommendations.

Affordability, access and quality of life
According to recent figures, the Government spent $585.9 million last year on chemotherapy drugs listed on the PBS. And while coronary heart disease is the single largest cause of death among Australians, accounting for 15.6 per cent of deaths, all forms of cancer combined account for approximately one-in-three deaths in Australia each year. For the estimated 120,000 Australians who will find themselves diagnosed with cancer this year, many will face exceptionally high out of pocket costs in order to access drugs necessary for their treatment.

The high cost of treatment adds additional stress to consumers already dealing with a difficult disease. In our submission to the Committee’s Inquiry into Out-of-pocket costs in
Australian Healthcare last year, we detailed the impact high costs of healthcare have on consumers.

The issues associated with expensive healthcare included general stress and anxiety, overstretched family budgets, and avoiding other, necessary treatments to save money. So for consumers who successfully recover from cancer or go into remission, the high cost of treatment might leave them in continued, desperate financial circumstances as they struggle to recover from the increasing cost of treatment.

We support policies and programs which encourage compassion towards those who are facing the challenges of life-threatening illnesses, no matter how common or rare, even if these drugs prove to be costly. The challenge lies in striking a balance between an analysis of ‘value for money,’ particularly recognising that it is dangerous to take a reductionist approach to assessing the value of one life over another.

**Operation of PBAC and the PBS**

While the mechanisms which affect the pricing of drugs are complex, they are largely driven by the PBS. Through the PBS, the Federal Government pays a fixed price rebate to the dispensing pharmacist for providing drugs to a consumer. This price is negotiated between the Government and the supplier of the medicine when it is listed on the PBS. As part of the process for listing a medicine on the PBS, PBAC makes the recommendations to the Minister for Health. PBAC is required by legislation to consider both the cost and effectiveness of the medicines under review for listing on the PBS.

However, PBAC cannot even begin to consider a medicine for listing on the PBS until it has been approved for registration and use in Australia by the Therapeutic Goods Administration (TGA). Furthermore, in the case of drugs whose cost to the Government, if listed on the PBS, may exceed $20 million per annum – which is not at all beyond the realm of possibility for drugs designed to treat very specific and/or rare forms of cancer – the drug requires additional Ministerial review and approval. In general, we believe the threshold for Ministerial review and approval ought to be revised and subject to both indexing and regular review.

The combination of review times by the TGA, PBAC, and potentially further reviews by the Minister have the cumulative effect of denying many Australians speedy access to the newest forms of cancer treatment.

Recently, it’s been proposed that drug availability in Australia be expedited by allowing the TGA to have increased reliance on ‘trusted overseas regulators’ in determining whether a drug ought to be registered in Australia. CHF appreciates that there may be circumstances where a broad consensus of overseas regulators concerning a medicine exists.

Where there is a particular, exigent need to make a medicine or medical device available to certain consumers, it makes sense to give added weight to overseas regulators in the approval process. As such, CHF recognises that there may be some advantages in moving towards a clearly articulated and well-structured, global harmonisation in some specific circumstances, such as the approval of specialty cancer drugs.
However, the conditions under which a medicine could be considered for and approved under the program ought to be clearly defined in legislation, to include the criteria for defining an ‘unmet medical need,’ which may include the need for specialist drugs to treat rare cancers, that would warrant the use of the accelerated program.

What’s important to keep in mind in all of these issues – from evaluating the ‘value’ of listing particular drugs on the PBS to determining whether a proposed drug or treatment meets the standards for accelerated consideration – is that the decisions made will affect consumers, people with very real and serious issues, and so their input to these decisions is of paramount importance.

Currently, the TGA has nine statutory advisory committees, each with consumer representatives. Three of these committees have a direct role to play in providing advice on the standards for making available new, innovative, and specialist drugs in Australia:

- Advisory Committee on Prescription Medicines (ACPM), which is the key committee that makes recommendations about the inclusion of prescription medicines on the Australian Register of Therapeutic Goods (the Register),
- Advisory Committee on the Safety of Medicines (ACSUM), which makes recommendations regarding the safety and risk assessment of medicines, and
- Therapeutic Goods Committee (TGC), which provides overarching advice to the Minister for Health on matters pertaining to therapeutic goods in Australia.

Each of these advisory committees has a single consumer representative. PBAC, too, has just one consumer representative and only three meetings per year to consider consumer input. This is wholly insufficient for allowing consumers to provide sufficient input to the process of having new, innovative and specialist drugs made readily available in Australia, listed on the PBS, or any future designs to accelerate the approval of new and innovative cancer treatments.

Furthermore, the meetings of TGA’s advisory committees and of PBAC are poorly advertised to the public in advance, and their decision-making processes not transparent. Equity and transparency needs to be evident in the advice given to the Government about how new cancer drugs are made available in Australia, particularly if there is a concern about costs or overall value and if TGA begins to rely more heavily on the decisions of international regulators in determining what drugs are to appear on the Register.

In deciding on whether to make a new, innovative and specialist drugs more readily available in Australia, the Federal Government must also improve the mechanisms to allow consumers to weigh in on those drugs and to relay their advice more expeditiously to policymakers.

We acknowledge that, in making these decisions, more evidence must be considered about the safety and efficacy of these drugs than the views of consumers alone, but these discussions and considerations are incomplete if they exclude or weigh against consumer input.
Conclusion
We recognise that there is a need to improve consumers’ access to new, innovative and specialist cancer drugs. However, there are many factors to consider in designing a regime that will make such access quick, safe, cost-effective and reasonably assure consumers battling cancer a better quality of life. As cancer will remain a very significant health concern well into the future, the Federal Government must be prepared and ready to acknowledge that the long term costs associated with the burdens of cancer.

The choice before the Federal Government in managing these costs, though, is to either improve the subsidisation of cancer drugs, thus alleviating the long-term impact on the health system, or preparing for consumers who will increasingly struggle with the costs of cancer treatment to present to the health system with more acute symptoms and other burdens of disease.

Consumers are central to the discussions about these choices and must be included in consultations about the future.

Recommendations
The Consumers Health Forum recommends that:

- **Mechanisms for consumer involvement** in debates and decision making about the availability of cancer drugs and treatments in Australia be significantly enhanced, and that support be provided for consumer engagement,
- **Transparent measures** for assessing the value of cancer drugs and treatments that go beyond the dollar figures and include measures concerning the quality of life and long-term impact on the health system be developed, in partnership with consumers, and
- **Pathways for evaluating** and making available new cancer drugs and treatments into Australia be harmonised with evidence-based, best practices from around the world.
About CHF

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian health care consumers. CHF works to achieve safe, quality, timely health care for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable health care
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members’ knowledge, experience and involvement
- development of an integrated health care system that values the consumer experience
- prevention and early intervention
- collaborative integrated health care
- working in partnership

CHF member organisations reach Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.