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# BRISTOL-MYERS SQUIBB AUSTRALIA'S SUBMISSION ON INITIAL FINDINGS OF THE *ACCESS TO CANCER MEDICINES IN AUSTRALIA* REPORT

The following submission represents Bristol-Myers Squibb's (BMS) response to the initial findings of the *Access to Cancer Medicines in Australia* report released by the Medicines Australia Oncology Industry Taskforce on July 31, 2013.

## BMS and Oncology

There is an ongoing need for new treatments and therapeutic modalities for patients with advanced cancers. While surgery, radiation and cytotoxic/targeted therapies have been the mainstay of treatment in most advanced cancers, mortality remains high for many patients with advanced solid tumours. Indeed, for several common cancers, 5-year survival rates continue to remain below 20% for patients with metastatic disease (lung 3.9%, colorectal 12.5%, renal cell 12.3%, melanoma 16%)[1].

BMS has been on the leading edge of cancer treatment since the 1970s and continues to be committed to discovering, developing and delivering innovative medicines for the treatment of cancer. BMS's pipeline in oncology is robust, with approximately 10 experimental anticancer compounds in development. It is also diverse, reflecting a range of modalities and research programs. One such area is immuno-oncology.

Current cancer treatment modalities include radiation, surgery and chemotherapy/targeted therapy, all of which are intended to target the tumour. Immuno-oncology is different because it uses the natural capability of the patient's own immune system to fight the cancer.

Immuno-oncology is an emerging therapeutic modality being studied for its potential in the fight against cancer. Understanding how cancer evades the immune system is the foundation of immuno-oncology. BMS hopes to find new ways to stop cancer from evading the immune system, thereby restoring the body's natural ability to promote tumour destruction.

It is in the context of new and emerging treatment mechanisms that BMS provides these comments. To fully avail the oncology community with such advances, the reimbursement system must focus on communication, retain a measure of flexibility and adaptability in approach, and ensure that solutions can be found to ultimately ensure timely access.

[1] http://www.immunooncology.com/clinicalneed.aspx

## BMSA's comments on the Initial Findings of the Report

The *Access to Cancer Medicines in Australia* report highlighted many of the issues and opportunities that Australia faces in the future with respect to the funding of, and access to, new oncology medicines. In summary the document reported that:

- **Australia has the highest age-standardised incidence of cancer in the world, resulting in significant disease and economic burden**
- **The process of discovery and development of medicines is complex, time-consuming, and typically high-risk, particularly for cancer medicines**
- **There is a range of issues affecting timely and affordable access to cancer medicines in Australia, particularly for new cancer medicines**
- **If these issues are not addressed, many stakeholders believe that Australia will fall behind other countries in cancer outcomes in the future, and**
- **Many stakeholders suggest a need to adapt and evolve registration and reimbursement processes alongside the development in technologies for the future**

BMS views the PBS as the cornerstone of the Australian healthcare system – providing affordable access to cost-effective medicines for all eligible Australian patients.

BMS agrees with the report's conclusion that the growing prevalence and burden of cancer, emergence of new high cost cancer medicines, and increasing expectations for early access by Australia patients, will place significant pressure on the PBS system into the future.

As such, BMS endorses the Medicines Australia Oncology Initiative to engage all relevant stakeholders in discussions around access to cancer medicines in Australia - with the view to working towards potential solutions that allow access to future medicines that extend and enhance Australian lives.

## Additional areas for discussion within the Oncology Initiative

### *Early communication: pre-submission efforts to reduce re-submission cycling*

A key workstream that BMS proposes for future discussion relates to a review of the current pre-PBAC submission process. BMS believes that integration of all relevant stakeholders in a '*solutions-orientated*' pre PBAC submission round table would lessen the current PBAC submission 'churn' that currently sees a PBAC approval rate in the area of oncology sitting at ~ 20%.

BMS believes that changes to the current process could include:

i) earlier engagement (e.g. pre Phase III clinical trials);

ii) broader engagement (e.g. TGA, PBAC, doctors, patients, sponsor companies); and

iii) solution specific agreements (e.g. pre-defined agreement on Main Comparator; data requirements; post marketing commitments, etc).

Clearly, this approach requires a change in ethos from all stakeholders and while potentially more resource intensive up-front, it should significantly lessen PBAC submission 'churn', and importantly, deliver faster access to cost-effective medicines for Australian patients.

***Adaptability and flexibility in approach***

As innovation in oncology delivers new and different mechanisms, pathways and targets, it is critical to ensure that the system retains sufficient flexibility and adaptability. The system may be perceived to move too slowly in ensuring that the evaluation is fit for purpose; that is, determining the same type of decisions but ensuring the process and evaluation suits that innovation. Early and considered discussion about what will best deliver information to ***enable*** decision making is important, as too is the need for flexibility.

We suggest that at times, applying traditional methodologies may be neither efficient nor fit for purpose. Informing the PBAC about new modalities, targets and outcomes within a submission is inefficient and inadequate. However, there is currently no alternative to ensure evaluators and key committee members are i) able to educate others involved in the review process and ii) able to agree the right methodologies to most appropriately inform the final PBAC decision.

From time to time, the system does exhibit some flexibility but this is inefficient, incomplete (across the system) and slow. This leads to the ironic outcome that those therapies that are more distinct, different or innovative are differentially disadvantaged as it takes time and investment for system adaptation.

***Solution orientated approach***

In oncology the goal or objective is consistently about affordable and timely access and importantly is a shared goal across all stakeholders. BMS submits that the system processes could be re-assessed to ensure greater space for discussion and agreement. This ought to remove the PBAC submission 'churn' previously discussed, or at least reduce it. While pre-submission approaches are critical, the same solutions orientation must be applied throughout the PBS listing process.

BMS has experienced the positive benefits of solution-oriented approaches, and while difficult and challenging at times, the overall goal or objective is more likely to be achieved in a more timely manner.

## Conclusion

It is widely agreed that cancer is a major public health issue in Australia. While past investment has seen Australia become a world leader in cancer research, prevention and care, future investment is required to ensure that Australia's standing remains.

The *Access to Cancer Medicines in Australia* report is a significant body of work that has assisted in starting the discussion around the anticipated challenges and opportunities associated with future access to cancer medicines. BMSA encourages the continuation of this cross-stakeholder debate.