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Novartis Pharmaceuticals Australia Pty Ltd

Submission to Oncology Industry Taskforce: Response to Deloitte Access Economics report, *Access to cancer medicines in Australia (July 2013)*

Novartis Pharmaceuticals Australia welcomes the opportunity to comment on the recent (July 2013) Deloitte Access Economics report titled, *Access to cancer medicines in Australia*.

Novartis is a diversified healthcare company, employing nearly 120,000 associates worldwide, with 1,000 employed in Australia. Our medicines help address a wide variety of disease areas and we are one of the leading global innovators in cancer medicines.

The Novartis Oncology business unit has a presence in more than 55 countries (including Australia), with approximately 7,000 associates globally (100 employed in Australia) dedicated to oncology related research and development. With over a decade of experience, Novartis Oncology has provided significant investment into clinical trials in cancer care in Australia and continues to invest, with ongoing active trial sites throughout the country. In 2013, this investment will be over $10 million. Not only does this investment support early patient access to new cancer medicines, it also provides clinicians valuable experience with new medicines.

Novartis is a member company of the innovative medicines industry association, Medicines Australia, and a founding member of the Oncology Industry Taskforce.

Novartis has firsthand experience of many of the issues raised by the recent report from Deloitte Access Economics. Novartis joined the Oncology Industry Taskforce because we believe that Australians living with a cancer should have timely, affordable and equitable access to new cancer medicines. We acknowledge that many other stakeholders including Government, clinicians, patients as well as industry partners also share this objective. This is why Novartis supports the recommendation of the report to ensure there is a multi-stakeholder discussion about the value of cancer medicines to the Australian community.

The following submission details some of the issues and challenges that Novartis considers should be prioritised in the multi stakeholder discussion. We have also used this opportunity to suggest some concepts that could be considered when discussing solutions. The intention of our submission is to support a constructive dialogue between industry, Government, clinicians, patients and the general public.

At the outset, Novartis would like to acknowledge and welcome the election commitments made by the new Coalition Government regarding the restoration of integrity to the PBS process. In addition, the pledge to give the Health Minister authority to list medicines that do not cost more than $20 million in

their first four years. We hope these measures will be implemented swiftly as they will provide benefit to cancer patients (as well as those patients with rare diseases). However, Novartis asserts that a deeper review of the PBS and related systems and processes is required to ensure savings made elsewhere in the system (particularly as a result of recent price disclosure measures) are used to fund new cancer medicines.

In recognition that a deeper review may take time, Novartis recommends that stakeholders should consider the value of implementing a cancer drugs fund similar to the model in England, which has recently been extended until 2016. The UK Prime Minister, David Cameron, has said that the cancer drugs fund had been a "massive success" and added that should he be re-elected he would recommend that it be continued beyond 2016[1].

The existence of the English NHS cancer drugs fund is indicative of the challenge that current health technology assessment methods and processes have in working effectively for cancer and other specialist medicines – one of the main areas highlighted in the report. Such a fund for Australia would ensure patients have timely access to cancer medicines, while a sustainable solution is sought.

Key Issues and Challenges

Introduction

As the Deloitte Access Economics report explained and as many stakeholders noted, cancer is an area of high unmet clinical need in Australia. Despite improving survival rates, cancer remains one of the leading causes of deaths in Australia. The report also highlights that cancer accounts for about one fifth of the total burden of disease in Australia. With Australia's ageing population, this trend is likely to increase.

The Pharmaceutical Benefits Scheme (PBS) has long been considered the gold standard in providing equitable and affordable access to medicines for Australians. Unfortunately this position has been eroded in recent years as many countries around the world have recognised and acted to anticipate the impending challenges that lie ahead with regards to access to cancer medicines. In contrast, countries such as England, Scotland and Canada have implemented new funding models for cancer medicines. As the Deloitte report outlined, there are now significant access gaps appearing between Australia and other countries.

For example, everolimus (Afinitor® – Novartis) for second line advanced kidney cancer is now reimbursed in Austria, Bahrain, Belgium, Bulgaria, Canada, Czech Republic, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxemburg, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, Taiwan, UK, and the USA, but has yet to

[1] Cancer drugs fund 'to be extended' until 2016, BBC News Website: http://www.bbc.co.uk/news/health-24304351 (Accessed 29 September 2013)

be reimbursed in Australia, despite four PBAC submissions. There are many other similar examples cited in the report, with more to follow unless there is change to the current status quo.

While Novartis currently provides everolimus to Australian kidney cancer patients via a patient co-pay access scheme, we also provide 'full donation' access for over 550 cancer patients in Australia. The value of these medicines will be approximately $10 million in 2013. This situation is not sustainable and suggests that there are issues that need addressing. Hence the need for an inclusive dialogue to ensure a sustainable solution to ensure value for all stakeholders.

Government Priorities and Cancer Australia

Cancer is recognised by the Government as a National Health Priority Area. The Cancer Australia Act was established in 2006 by The Hon. Tony Abbott MP when he served as Minister for Health and Ageing. Cancer Australia has a budget of roughly $30 million and was established to deliver eight functions. Three of these functions pertain to patient access to cancer medicines i.e. 1) provide national leadership in cancer control, 2) coordinate and liaise between the wide range of groups and health care providers with an interest in cancer, and 3) to make recommendations to the Commonwealth Government about cancer policy and priorities[2].

To date, Cancer Australia have not engaged in this critical area of cancer control. Therefore, Cancer Australia should be considered a critical stakeholder in any ongoing dialogue and discussion regarding timely, affordable and equitable access to new cancer medicines.

Understanding the cost of cancer to the community

The report estimates the total expenditure on cancer in 2012 was $4.7bn. However, the report concedes that this does not include the real cost of cancer to the community. There are significant costs that are rarely quantified such as informal care, travel costs for patients (which can be significant for patients from outside the cities receiving ongoing care) and, most importantly, there is a lack of understanding with regards to the impact of lost productivity due to cancer for both patient and carer. Further research is required to understand the real financial burden of cancer on the community.

Cancer and the PBS

According to the most recent published data from the Pharmaceutical Benefits Scheme (2011-12), the total annual PBS expenditure on medicines was $9.2 billion[3]. However, the report indicates only 13% ($707 million) was spent on cancer medicines. This is despite cancer accounting for about one fifth of the total burden of disease in Australia. As the report points out, musculoskeletal diseases accounted for 13% of health expenditure, but only 4% of the burden of disease.

[2] Cancer Australia Act 2006: http://www.comlaw.gov.au/Details/C2006A00035 (Accessed 29 September 2013)

[3] Expenditure and prescriptions twelve months to 30 June 2012: http://www.pbs.gov.au/statistics/2011-2012-files/expenditure-and-prescriptions-2011-2012.pdf (Accessed 25 September 2013)

With the recent significant pharmaceutical patent expiries and price disclosure there is an opportunity for the Government to use these substantial savings to pay for new cancer medicines.

The new paradigm of cancer research and associated challenges

As the report explained, cancer research and development has fundamentally changed, particularly due to the rapid advances in our understanding the genomics of cancer. Working from the human genome, researchers have gained an understanding of the complete genetic makeup of human cells, which has provided a new roadmap for current cancer medicine design.

As the scientific community understanding of these new technologies grows, targeted (or personalised) cancer medicines have become the new paradigm. New cancer medicines may now specifically inhibit pathways (e.g. HER2 pathway) in the body rather than just at a tumour site (e.g. breast cancer).

By focusing on specific pathways it means that patient populations with which these medicines are beneficial are smaller, thus creating challenges in clinical trial design as well as patient recruitment. As the report suggested, this also leads to relatively higher levels of evidentiary uncertainty compared to medicines developed in the past. Novartis would agree with stakeholder opinion in the report that suggests the current system is not sufficiently sensitive enough to assess the complexity of many cancer treatments, particularly for medicines intended to treat small patient populations.

Unfortunately systems by which we assess these new technologies have not kept pace with these dramatic changes. For example, the PBS was established in 1948. In 1993, it became mandatory for sponsors to provide economic evaluation in submissions to Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC process applies the same evidentiary requirements to all drugs, with no special considerations for cancer drugs. Over the years the evidentiary expectations and complexity of analyses have increased for all medicines. This is now overlayed with the requirement for assessment of any associated companion diagnostic.

Novartis recommends a review of methodologies and evidentiary requirements to ensure the reimbursement system is sufficiently sensitive enough to assess the complexity of cancer treatments, particularly for medicines intended to treat small patient populations. Whilst recognising the recent work of MSAC to review their system and processes, it will also be critical for any review to include requirements for companion diagnostics.

Overall survival (OS) is often considered by payers to be the most clinically relevant and meaningful endpoint for cancer medicines. However, it's been recognized by many other stakeholders, particularly clinicians, that there are significant limitations and challenges associated with achieving this endpoint. As the report highlights, measuring OS substantially prolongs the duration of the trial, increases the number of patients needed to be recruited and amplifies the cost of completing the trial. Furthermore, collection of OS data may be precluded by the trial committee if they decide to terminate the trial (due to ethical considerations) once progression free survival (PFS) has demonstrated substantial benefits.

Ethical considerations also play a role in the clinical trial design by allowing patients to cross over to active treatment when the patient's disease progresses. This confounds the ability to measure OS.

As discussed in a recent article from the Journal of Clinical Oncology, a clear distinction ought to be made among survival as a goal desired by patients, clinicians, clinical trialists, and public health policymakers[4]. Each of these groups has different perceptions of overall survival. All of these views, definitions and questions should be considered when making access and funding decisions for cancer medicines.

As a result of cancer medicines becoming more targeted to specific pathways it is no longer possible for a clinical trial to recruit large patient populations. Therefore it is challenging to generate evidence from large multicentre phase three randomized controlled trials in this setting.

The Food and Drug Administration (FDA) in the USA has acknowledged this new paradigm in cancer research and has recently restructured their processes to expedite the development and review of drugs for serious or life-threatening conditions (i.e. 'FDA Breakthrough Therapy' designation). This has also resulted in approvals being granted for cancer medicines based on surrogate endpoints and early clinical trial data. It is acknowledged that further post-approval evidence may be required from the sponsor for this to happen, but the sponsor accepts the FDA registration on the basis of this commitment. This proactive approach from the regulators has helped the FDA to greater understand the cancer medicine pipeline, as well as anticipate their resource requirements into the future. However, this now means Australia lags further behind the USA in relation to the availability of new cancer medicines.

Unfortunately we do not have a system in Australia to differentiate or prioritise therapies like the FDA's 'Breakthrough Therapy' designation.

Novartis recommends that there should be a review in relation to identifying and prioritising medicines for regulatory and reimbursement evaluation for medicines treating conditions of unmet medical need. A designation such as the FDA's 'Breakthrough Therapy' status could be considered for the TGA to ensure medicines treating conditions with clear unmet clinical and patient needs are prioritised in the system.

Access to Co-Dependant Technologies

As previously outlined, the new paradigm of cancer research requires new thinking to ensure all patients who may benefit from a medicine can affordably access the cancer medicine. The pivotal feature of new personalised medicines is that a group of patients who will derive a benefit from the medicine can be defined by an associated diagnostic test. Not only does this provide greater certainty for the patient and the clinician as to whether a medicine will provide a benefit, it also minimises any wastage in the

[4] Saad ED and Buyse M, Overall Survival: Patient Outcome, Therapeutic Objective, Clinical Trial End Point, or Public Health Measure? Journal of Clinical Oncology, Vol 30, 2012.

system, thus leading to greater efficiencies. In the majority of cases, as the technologies are new, the diagnostic test may not be funded by the relevant reimbursement system i.e. the Medicare Benefits Schedule (MBS). However, this issue is further complicated by the fact that medicines are reimbursed through a separate reimbursement system i.e. the Pharmaceutical Benefits Scheme (PBS).

As the report highlighted, the challenges associated with the complexities of two systems to evaluate co dependant technologies are considerable. For example, the process of evaluating diagnostic tests for reimbursement under the MBS alone takes at least 51 weeks before a listing, and the PBAC will not recommend a medicine to be listed until the associated test is listed on the MBS.

Novartis acknowledges the progress made by the PBAC and MSAC to streamline the system, but further action is required to remove complexities in the process and ensure there is greater flexibility and coordination in the system so that patients are not denied access to medicines due to procedural issues[5].

Measuring the value of cancer medicines

Whilst the report cites a number of stakeholders suggesting cancer medicines are expensive, especially for new targeted therapies, the focus of the discussion should be on the value of new cancer medicines, particularly targeted therapies. Older, non-targeted cancer treatments (i.e. IV chemotherapy) often made patients very sick and required costly hospitalisations for both administration and for the treatment of side effects. These have been replaced with targeted drugs with more manageable side effect profiles and in many cases are oral medicines that can allow patients to be more easily treated at home. Not only do these advances provide savings to the health budget, they also provide significant value to the patients being treated. This is especially true in Australia, where many patients have to travel significant distances to be treated.

The value of medicines to patients is a critical consideration, but the value to the broader community is also important. Novartis is very supportive of greater community involvement in the decision making process regarding the availability, reimbursement and ongoing use of cancer medicines. We support the current consumer engagement in the PBAC process via online comments. However, more can be done to encourage greater community awareness and education of, as well as engagement in, the process.

An ongoing community discussion is required regarding the value of cancer medicines to society. The community needs to consider what should be acceptable levels of funding for caring for cancer patients, particularly those with advanced cancers. These perspectives should be used to enhance and inform decisions made within both the regulatory and reimbursement process.

Recommendations

[5] Merlin T, Farah C, Schubert C, Mitchell A, Hiller J, Ryan P. Assessing Personalized Medicines in Australia: A National Framework for Reviewing Co-dependent Technologies. Med Decision Making 2013;33:333–342.

In summary Novartis would like to make the following recommendations for consideration by stakeholders as discussions progress:

- Facilitation (perhaps via Cancer Australia) of an ongoing, structured, transparent dialogue between all stakeholders to ensure Australian cancer patients have timely, affordable and equitable access to new cancer medicines.
- Facilitation of a public debate about the value of cancer medicines to the Australian community.
- Implementation of an interim cancer drugs fund (similar to the English model), to ensure patients can access medicines while discussions to find a sustainable solution are held.
- Consideration by the Government to use the savings made by PBS price disclosure to support new cancer medicines.
- Recognition and multi stakeholder discussion to find a timely and effective reimbursement system for co dependant technologies.
- Conduct further research to understand the real financial burden of cancer on the community.
- Review methodologies and evidentiary requirements to ensure the reimbursement system is sufficiently sensitive enough to assess the complexity of cancer treatments, particularly for medicines intended to treat small patient populations.
- Remove complexities in the process and ensure there is greater flexibility and coordination in the system to reimburse co-dependant technologies so that patients are not missing out on access due to procedural issues.
- Identify and prioritise medicines for regulatory and reimbursement evaluation. A designation such as the FDA 'Breakthrough Therapy' status could be considered to ensure medicines with clear unmet clinical and patient needs are prioritised in the system.
- All stakeholders have a responsibility to encourage greater community awareness and education of, as well as engagement in, the process by which medicines are registered and reimbursed in Australia

Novartis is committed to listening, acting and collaborating with all stakeholders to ensure patients to ensure Australian cancer patients have timely, affordable and equitable access to new cancer medicines.

Please note that Sandoz (a Novartis company) will make a separate submission to the Oncology Industry Taskforce.