SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

SUBMISSION

SUBMISSION NUMBER: **29**

SUBMITTER

Amgen Australia Pty Ltd

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October 20, 2010

Attention: Ms Naomi Bleeser
Senator Claire Moore
Chairperson
Senate Community Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

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Senate Community Affairs Legislation Committee Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

Dear Senator Moore,

Amgen Australia welcomes the re-referral of the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* to the Committee following the Bill's re-introduction on 29 September 2010.

Please find attached a submission from Amgen in support of the legislation.

Should you require any information about this submission, please contact Ms Sara Pantzer, Head, Government Affairs & Policy. Ms Pantzer can be contacted on 02-9870 1923 or 0407 891 625.

Yours sincerely

Ian Thompson
Managing Director, Australia & New Zealand

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Submission to the Senate Community Affairs Legislation Committee

October 20, 2010

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Executive Summary

A biotechnology pioneer since 1980, Amgen was one of the first companies to realise the new science's promise by bringing safe and effective biological medicines from lab, to manufacturing plant, to patient, and is now a leading human therapeutics company in the biotechnology industry.

Amgen's protein-based therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses.

Amgen is, and will remain, a leader in developing the next generation of biological medicines for these conditions.

The rapid emergence of biological medicines presents challenges for both government and industry. For government, these challenges relate to evaluation and funding on the basis of still evolving economic evidence, effective management of risk/uncertainty, and the overall fiscal context of the PBS.

For industry, the challenges relate to ensuring that Australian patients gain access to their products in a timely fashion, and justifying the high cost of these medicines within the current reimbursement framework.

More innovative reimbursement approaches will be required to enable these medicines to reach Australian patients.

It is for this reason that Amgen believes the changes proposed in the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should be supported.

The legislation is part of a package of measures (a 4-year Memorandum of Understanding between MA and the Government) which will deliver a range of initiatives to improve the listing process so that innovative medicines reach patients sooner. These are important in the Australian context because of the unique features of the regulatory and reimbursement systems, particularly the time it takes to achieve reimbursement status.

The MoU also provides a certain policy environment for a sector which must take a long term view of its R&D investment, given the length of time it takes to bring a medicine to market.

Amgen supports the position put by its industry association, Medicines Australia, in the MA submission requesting the Senate Committee to recommend passage of the legislation without amendment.

Introduction

About Amgen and biological medicines:

A biotechnology pioneer since 1980, Amgen was one of the first companies to realise the new science's promise by bringing safe and effective biological medicines from lab, to manufacturing plant, to patient, and is now a leading human therapeutics company in the biotechnology industry.

Before the availability of modern biotech medicines, there were many diseases that we could not treat at all, or we could only relieve symptoms without actually treating the underlying condition. [1]

Amgen's protein-based therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses.

Amgen is and will remain, a leader in developing the next generation of biological medicines for these conditions.

Amgen began in Australia, 1991 and now has offices in every major capital city.

It employs 200 highly skilled people, of which around 50% are engaged in the R&D side of the business. Many are science based graduates.

Amgen invests more than 15% of its Australian sales - or around $A35 million - in the discovery and development of new therapies, making it one of the largest R&D investors in this sector in Australia.

Amgen began clinical research work in Australia in 1987 before it officially opened here in 1991. In the early days it carried out phase I and II clinical trial work for Neupogen®, (which helps reduce the incidence of infection in patients undergoing certain cancer chemotherapy).

Today, it attracts a disproportionate share of the global corporation's clinical trial activity. Approximately half of its Australian clinical research activity is in early phase 1 or 2 trials.

[1] For example, damaged kidneys do not make enough of a protein called **erythropoietin (EPO)**, which tells the bone marrow to increase red blood cell production.. People with kidney failure, in addition to all of their other complications, don't make enough EPO in their kidneys, and as a result they have fewer red blood cells than normal. Using biotechnology, we can now use recombinant EPO to stimulate the production of red blood cells and treat chronic anemia among very sick patients with chronic kidney disease. Before EPO was available, very little could be done to help these patients and treat the fatigue of anemia.

Why the legislation is worthy of support

Amgen believes that the changes proposed in the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should be supported because they are part of a package of measures (a 4-year Memorandum of Understanding between MA and the Government) providing policy certainty to our sector, and access improvements for patients.

1. *Policy certainty:*

Given the long term and risky nature of the R&D effort in developing new medicines, biotech companies such as Amgen flourish best in an environment which provides long term certainty and stability for its R&D investment.

Research and development is a major component of Amgen's activities in Australia. Australia is amongst one of the highest contributing countries to clinical trial activity in the Amgen world, with the Australian subsidiary consistently contributing 10 per cent of clinical trial patients to the global pool of studies in which we participate. In many cases, the Australian clinicians are the first to enrol a patient in an Amgen study globally.

Amgen Australia contributes approximately 5 times more patients to clinical studies than the Australian industry average.[2]

Measures such as the MOU reinforce the certainty and stability of the environment, at a time when other countries are aggressively competing for the clinical trials business. [3]

2. *Benefits to patients from improved access:*

As the Minister notes in her second reading speech[4], the MOU contains further process and policy changes for the listing of PBS medicines which will reduce red tape and further foster the availability of new medicines in Australia.

These are important in the Australian context because of the unique features of the regulatory and reimbursement systems, particularly around the time that it takes to achieve reimbursement status.

Amgen would like to highlight three of those changes and demonstrate how they will improve access for Australian patients:

(a) Parallel TGA and PBAC processes

The MOU provides that from 1 January 2011, the Commonwealth will no longer require the respective registration and reimbursement evaluation and assessment processes for major submissions to be undertaken sequentially.

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[2] Global Clinical Metrics & Reporting and CMR International, 2010 Global Clinical Performance Metrics

[3] Over the last few years, we have seen Australian clinical trial registrations drop significantly, while other clinical trial destinations have become increasingly competitive (over the same time period, global clinical trials in Korea have doubled in two years).

[4] Second reading speech, House of Representatives, Sept 29,2010, 5

The ability to proceed with the reimbursement process without having to await the TGA process means that the overall listing time for products will be reduced. This is of benefit to patients who will receive access to the subsidised medicine sooner than under the current system.

This is also of real benefit to companies with complex products. Complex products may need to return to the Pharmaceutical Benefits Advisory Committee (PBAC) several times before they are successful and the potential for earlier commencement of the economic evaluation process will enable discussion and negotiation to complete earlier.

For example, Amgen has a PBS listed product for the treatment of patients with secondary hyperparathyroidism (SHPT), called Sensipar (cinacalcet). SHPT is a disorder that develops in chronic kidney disease (CKD) patients on dialysis and results in increased secretion of parathyroid hormone (PTH), which may lead to bone disease, bone pain and fractures, and cardiovascular problems .

Three submissions to the PBAC were required before Sensipar achieved a positive PBAC recommendation in July 2008, some 3 years after it was reimbursed in Germany and other EU countries Had the opportunity existed for parallel TGA and PBAC processes, Australian patients may have had earlier access to Sensipar.

(b) Managed Entry Scheme

Through the MOU, the Government has committed to introduce a Managed Entry Scheme from January 2011, as an additional tool for managing uncertainty in the PBAC decision making process.

A Managed Entry Scheme essentially allows the listing of a new medicine with a commitment by the company to generate and submit additional cost-effectiveness related data following listing

The initial circumstances where this facility will be available are when:

- the PBAC would not otherwise recommend the listing of the drug at the proposed price because the extent or value of the clinical effect is uncertain. This could be in instances where changes in surrogate endpoints have been extrapolated to patient relevant outcomes; and
- there is a randomised clinical trial (or comparable “fit for purpose” evidence), due to report within a reasonable timeframe, which the PBAC is satisfied will resolve an identified area of uncertainty.

This scheme, which in other countries is called “Coverage with Evidence Development” will be particularly helpful for certain biological medicines.

This scheme is required because it is often difficult for many complex biologics and targeted therapies to have sufficient cost-effectiveness evidence requirements, at the time of submission.

For example, the standard of care used in a Phase III clinical trial may have changed by the time the medicine reaches the market. This means that the comparisons sought by the PBAC to prove cost effectiveness will not have been undertaken.

Similarly, many biologics and targeted therapies are developed for low incidence disease often for end-of-life conditions with low life expectancies, thus placing a practical limit to the size and duration of clinical trials.

This often limits the quantity of clinical trial data on patients' overall outcomes available at the time of submission, and in many cases there will be a reliance on study measurements that meet the regulator's needs for assessment of efficacy and safety but not necessarily for cost-effectiveness.

A Managed Entry Scheme may provide a platform for addressing the uncertainties for the PBAC whilst allowing earlier access to the medicine for Australian patients.

The reimbursement of Sensipar® represents an early example of the benefits which a managed entry scheme might deliver. Sensipar® received TGA registration for the treatment of secondary hyperparathyroidism in dialysis patients based on phase 3 studies that demonstrated effective reduction of a biochemical measure (parathyroid hormone, a surrogate endpoint).

Unlike regulatory authorities, the PBAC ideally required data on patient relevant outcomes (mortality and morbidity) to reimburse Sensipar®. At the time of the submission, Amgen had commenced a study to determine the effect of Sensipar® on morbidity and mortality in dialysis patients, but was not expected to complete until 2011. The PBAC granted reimbursement for Sensipar® in 2008 in the knowledge that the definitive study was ongoing and with a request that Amgen would provide the results of the study to the PBAC.

The reimbursement of targeted therapies and biological medicines will require the use of innovative reimbursement approaches such as the Managed Entry Scheme if the system is not going to lead to delayed access to these medicines.

(c) Impact of F2 pricing reductions on the listing of new medicines

To achieve PBS listing, a company must provide evidence that a medicine meets the test of cost effectiveness. A medicine is considered acceptably cost-effective by the PBAC if the improvement in health outcomes justify the additional costs (and any additional harms) compared with its main alternate therapy.

As the economic evaluation of a new medicine is assessed by comparison with an existing treatment, it follows that where a new medicine is compared with an existing F2 medicine, it becomes increasingly more difficult to show cost effectiveness as the cost of the comparator medicine falls. This can lead to medicines not being listed for Australian patients.

The MOU provides the mechanism to ensure that price reductions in F2-listed medicines do not adversely impact the listing of new medicines. The MOU outlines a commitment for the Commonwealth and Medicines Australia to work together to formally document the impact on pricing of lower comparator prices.

Conclusion

In line with MA's submission, Amgen requests that the Senate Committee recommend passage of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

because the legislation is part of a package of measures (a 4-year Memorandum of Understanding between MA and the Government) which will deliver a range of initiatives to improve the listing process so that innovative medicines reach patients sooner, as well as a certain policy environment for the next 4 years.