Janssen-Cilag Australia

Submission to the Senate Community Affairs Committee Inquiry into Consumer Access to Pharmaceutical Benefits

31 March 2010

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.
In meeting their needs everything we do must be of high quality.
We must constantly strive to reduce our costs
in order to maintain reasonable prices.
Customers' orders must be serviced promptly and accurately.
Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.
Everyone must be considered as an individual.
We must respect their dignity and recognize their merit.
They must have a sense of security in their jobs.
Compensation must be fair and adequate,
and working conditions clean, orderly and safe.
We must be mindful of ways to help our employees fulfill
their family responsibilities.
Employees must feel free to make suggestions and complaints.
There must be equal opportunity for employment, development
and advancement for those qualified.
We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.
We must be good citizens – support good works and charities
and bear our fair share of taxes.
We must encourage civic improvements and better health and education.
We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.
Business must make a sound profit.
We must experiment with new ideas.
Research must be carried on, innovative programs developed
and mistakes paid for.
New equipment must be purchased, new facilities provided
and new products launched.
Reserves must be created to provide for adverse times.
When we operate according to these principles,
the stockholders should realize a fair return.

Table of Contents

1. Submission Information

Organisation: Janssen-Cilag Australia

Type of Organisation: Proprietary Limited Company

Address: 1 – 5 Khartoum Road, North Ryde NSW 2113

Declaration of Interest:

Janssen-Cilag Australia is engaged in business located in Australia and is the sponsor of a number of medicines listed on the Pharmaceutical Benefits Schedule.

Note:

Each product referred to in this submission is the Registered Trademark of Johnson & Johnson.

2. Janssen-Cilag Australia Overview

"Caring for the world, one person at a time".

Driven by our Statement of Caring, Janssen-Cilag Australia embraces research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Janssen-Cilag Australia is a leading research-based pharmaceutical company, employing more than 300 staff across Australia.

Janssen-Cilag provides prescription medicines for a range of conditions including mental health, neurology, women's health, haematology, gastroenterology, and pain management. Four Janssen-Cilag medicines are included in the World Health Organisation's Essential Drug list.

The research conducted by Janssen-Cilag Australia has resulted in a number of critical medicines being developed and made available to the Australian public.

3. Janssen-Cilag and the Pharmaceutical Benefits Scheme

We believe our first responsibility is to the doctors, nurses and patients,
to mother and fathers and all others who use our products and services…

Our Credo

As reflected in our Credo, we believe our first responsibility is to patients, and ensuring continued, cost effective access to the latest treatments is key. This requires both a well-defined system of access to medicines and the continued developed of new and innovative medicines.

In order to continue to develop new and innovative products, companies such as Janssen-Cilag Australia seek a strong, transparent and stable PBS.

We therefore welcome the opportunity to contribute to PBS related enquiries to ensure it remains effective in balancing access to medicines, cost effectiveness and market certainty.

In this submission we raise ideas and recommendations for possible areas of refinement surrounding therapeutic groups in the PBS, with reference to other broader elements of the Australian government's medicines policy.

We have not raised every issue related to the PBS that concerns us. It is not feasible to do so and other submissions will address further issues.

We have noted and broadly support the submission made by Medicines Australia (MA).

5. The Impact of Therapeutic Groups on the PBS

The Pharmaceutical Benefits Scheme (PBS) is a key component of Australia's health system. It is recognised worldwide as a model for ensuring equitable and cost-effective access to medicines. The 2007 PBS reforms sought to further strengthen this system by driving competition, ensuring savings for government and consumers, and providing adequate certainty for suppliers of medicines.

The formation of new therapeutic groups (TGPs) threatens to undermine this balance having negative consequences for both consumers and suppliers of medicines.

Our key concerns in relation to TGPs are broadly: patient health, primarily ensuring the quality use of medicines; fiscal decisions impeding effective clinician decision making; and damage to the business environment which will ultimately lead to lesser outcomes for patients (and indeed payers).

The issues raised in this submission go to the core of one of the central objectives of Australia's National Medicine Policy, ensuring timely access to the medicines that Australians need, at a cost individuals and the community can afford. We believe that the introduction of further TGPs would undermine this objective.

Impacting consumers

The introduction of TGPs in essence is about cost reduction. It is focused on budget outcomes more than patient health outcomes.

TGPs essentially make the claim that any product within the TGP is interchangeable and switchable at a patient level. Whilst we will question the way in which this decision is made, even if the medicines in a TGP were perfectly interchangeable for all patients on a chemical level, a number of other concerns may face the patient. Medicines may differ in size, shape, colour and dosing which could lead to confusion and non-adherence issues, particularly with older patients or patients with mental difficulties. In some cases (and particularly in areas such as mental health) patients may resist switching and directions to switch may undermine the trust relationship between patient and clinician. These considerations are important when switching patients between treatment regimes and may, out of necessity, be side-lined due to cost considerations, even by treating clinicians.

TGPs may also lead to clinicians being effectively forced to consider the cost of medicines when prescribing to patients. When prescribing a new medication to a patient the clinician may be forced to choose a different medicine within the therapeutic group that does not attract a price premium in order to ensure affordability. This may particularly be the case in groups that cross formulary boundaries as the clinician may wish to prescribe a newer F1 listed medication and yet the high price premium may in effect force them to prescribe an older F2 listed medication. Clinicians are hardworking, busy professionals and time spent addressing issues other than the best available clinical treatment for their patient is precious and potentially costly.

These considerations may become even more critical in the case of patients already stabilised on a medication that is affected by cost reductions in a therapeutic group. In areas such as mental health, transplantation and epilepsy, once a patient is stabilised on a medication, even switching to an equivalent medication may cause issues of confusion, lack of compliance, loss of efficacy or increase in side-effects. Cost efficiency should not override these important considerations of patient safety.

Not only do these issues directly affect patients in the short term they will continue to have negative repercussions into the future.

The long-term nature of the pharmaceutical industry creates a heavy reliance on market stability. It can take 10 years and over $1 billion USD to develop a medicine, not including all the costs associated with educating clinicians about the medicine and providing after-market support. In order to ensure a return on investment businesses require reasonable certainty as to the position and price of such a product in the market. The patent system is main way that this stability is provided for. However, TGPs can cross the boundaries between the two formularies created in the PBS, thereby creating the possibility for patented medicines to be forced to take price cuts before the end of the patent period. This situation undermines the foundation of the pharmaceutical industry and protections provided in the patent system. Whilst this does not directly impact patients, the repercussions for patients could be quite serious.

The pharmaceutical industry is global and highly competitive. The instability that would be created by the introduction of further TGPs may result in multinational companies not launching products in Australia. This will directly impact consumers in Australia and block access to potentially lifesaving medications. This problem will only be exacerbated for companies with 'niche' medications for small patient populations where the return on investment is relatively low. Janssen-Cilag is one such company.

Similar considerations may also prevent companies bringing incremental innovations in medicines to market in Australia as they would be likely to be placed in TGPs. Key incremental innovations can have major impacts in areas such as efficacy, limiting side-effects and improving a medicine's shelf life or stability.

Many niche products are also, due to their nature, high cost medications. Consideration of the impact of TGPs on high-cost medicines reveals further issues that need to be carefully considered. Medicines suppliers, particularly those with medicines under patent affected by TGPs, may choose to charge a price premium to deliver price stability. This is particularly the case with high cost medicines. Patients will be forced to either pay the premium or switch to another medicine, which for reasons already outlined, is both unhelpful and undesirable.

There are provisions for clinicians to apply for an exemption to the premium under the safety net. However, this effectively undermines the system as the government will once again bear the cost, and the clinician and patient will be faced with an extra administrative step.

Increasing the number and size of patient contributions

Traditionally, patient premiums have been used quite sparingly in order to reduce the financial burden on the patient. However, as has already been suggested, it would be highly likely that the introduction of further TGP to the PBS would result in both an increase in the number and the size of patient contributions.

This will be especially the case if TGPs are created that span formulary boundaries. Companies may need to introduce more and higher premiums in order to reduce the impact of mandated price reductions generated by a medicine in the TGP shifting to F2 status. As already suggested, the result of these changes may simply create an extra level of paper work with no financial benefit to the government, as the safety net may be used to over ride the premiums. If the safety net is not utilised then the patients will be forced to bear this increased financial burden to maintain access to life savings medicines.

The issue of determining clinical interchangeability

Determining interchangeability is at the core of this issue. Regardless of the process or cost issues, if the medicines are not truly 'interchangeable' then the risk of adverse effects for patients should caution any move to create new TGPs.

Whilst there is no specific evidence as to how clinical interchangeability is determined, based on the formation of previous groups, a number of assumptions can be drawn. The legislation provides that TGP groups are formed by the Minister and the Minister may have regard to the PBAC. This would suggest that the evidence used is information provided to the PBAC which is provided by industry at the time of listing a medicine on the PBS.

This data is based on clinical trials and can provide a sound evidence base. However, once a medicine is in the market pharmaceutical companies continue to study and monitor the medicine, collecting updated information on how the medicine works in a wider patient population. The importance of this later monitoring is reflected in the way PI and label changes are made later in a products life cycle to recognise the further information gathered from having the product in a substantially greater patient pool than any trial could provide. This most recent information that pharmaceutical companies hold would provide a more accurate data set for any guidance on 'interchangeability'.

Additionally it must be assumed that the evidence provided to the PBAC for consideration in relation to TGPs is that designed to show that a medicine[1] is 'non-inferior'. This data cannot be used to suggest that a medicine is superior or equivalent or that it has the same side effect profile. This is because the information is designed to show a medicine's broad clinical and cost-effectiveness on a population level. This information is not targeted at individuals and as result should not be used as the basis for decisions on interchangeability at a patient level.

[1] Likely to be put in a TGP i.e. not a medicine considered clinically superior.

Therefore there are two problems. First is the question of transparency and process as there is a lack of evidence on how the Minister determines interchangeability. Secondly, considering that the Minister may draw on all evidence available to them, the ability of the information available to effectively and accurately determine interchangeability is not established. Not only that but it does not appear that the conclusion can be safely drawn that a patient may switch between medicines in a TGP with no adverse effects. This assumption is in direct conflict with underlying premise of the TGP policy.

The consultation process for new TGPs

The final comment to be made is one regarding the consultation process surrounding the creation of the recently established TGPs. The process undertaken by the government when forming the four most recent TGPs has set a dangerous precedent. The announcement of the new groups as part of the MYEFO came as a surprise as there had been no prior industry or broader stakeholder consultation about these new groups.

The Government should ensure that all health policy decisions are made using the latest available clinical evidence. The companies that make medicines would be best placed to provide current information to assist in understanding, and if strictly necessary, determining interchangeability.

An ongoing dialogue between government, industry and relevant stakeholders (including consumers) is the only way to ensure the long term viability of the PBS and to enable the partners in the National Medicines Policy framework to ensure its success.

6. Conclusion

Janssen-Cilag Australia supports a strong and effective PBS that provides the best available clinical treatment, cost effective access to medicines and reasonable certainty for industry.

We are deeply committed to working with governments and other stakeholders towards high standards of healthcare for all Australians and ensuring that companies in Australia can continue to provide innovative healthcare solutions.

In this spirit, we thank the Senate Community Affairs Committee for the opportunity to submit and we are pleased to provide this submission to the Committee for consideration.

Janssen-Cilag Australia would be pleased to assist and work with the Committee and the Government to:

1. amplify and/or clarify these submissions;
2. attend hearings to speak to these submissions;
3. provide expert advice in relation to these submissions or matters of the PBS; and
4. otherwise contribute to the development and implementation of an effective and balanced framework for medicines reimbursement in Australia.