Executive Summary

AstraZeneca welcomes the opportunity to contribute to the inquiry into the Government's administration of the Pharmaceutical Benefits Scheme, with particular reference to the recently implemented practice of deferring the PBS listing of medicines which have received a positive recommendation from Pharmaceutical Benefits Advisory Committee. It is our view that the policy of Cabinet deferral is likely to be largely ineffectual with respect to delivering savings to the PBS of a magnitude which will have a meaningful impact on the objective of returning the budget to surplus. Thus, the willingness of the Government to adopt such a policy, despite its potential to deliver worse health outcomes for patients at increased costs is a matter for significant concern. In particular:

1. **The deferrals policy undermines the role of the Pharmaceutical Benefits Advisory Committee.** The PBAC is internationally renowned for its rigour in assessing new medicines for Government subsidy and as such has been pivotal in supporting the objective of the PBS of delivering timely access to medicines that Australians need, at a cost individuals and the community can afford. By overriding the recommendations made by its own Expert Committee, the Government risks undermining the very system which is recognised throughout the world as a model for delivering optimal health outcomes in a cost-effective and equitable manner
2. **The deferral of the listing of Symbicort® for chronic obstructive pulmonary disease represents a missed opportunity for patients to benefit from improved health outcomes at a reduced cost to patients.** What is particularly concerning about the decision to defer the PBS listing of Symbicort® for COPD is that it suggests a preference to shifts costs from the Government to patients
3. **The deferral of the listing of Symbicort® for chronic obstructive pulmonary disease represents a missed opportunity for the Government to accrue savings to the PBS.** PBS listing of Symbicort® for COPD is predicted to result in savings to Government in the order of less than $10 million over the first 5 years of listing
4. **Cabinet deferrals introduce policy instability and significant commercial uncertainty which may result in delayed or diminished access to medicines for Australian patients**

Accordingly, please find below our responses to the stated terms of reference for the Inquiry for consideration.

a) The deferral of listing medicines on the PBS that have been recommended by the PBAC

Cabinet deferrals undermine the important role that the PBAC plays in supporting the objective of the PBS of delivering timely access to medicines that Australians need, at a cost individuals and the community can afford. The policy is unlikely to deliver savings of a magnitude which will have a meaningful impact on the objective of returning the budget to surplus, while delivering worse health outcomes for patients at increased costs to patients.

AstraZeneca would like to take this opportunity to express our concern over the recent decision by the Government to implement a policy of deferring PBS listing of medicines which have received a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC enjoys a formidable reputation internationally for its rigour in assessing new medicines for Government subsidy. The role of the PBAC is pivotal in supporting the objective of the PBS of delivering timely access to medicines that Australians need, at a cost individuals and the community can afford. The success of the PBAC in achieving this balance is supported by data which demonstrates that Australians do better in terms of key health indicators than the majority of their OECD counterparts whilst spending a significantly lower proportion of GDP on health. Thus, by overriding the recommendations made by its own Expert Committee, the Government risks undermining the very system which is recognised throughout the world as a model for delivering optimal health outcomes in a cost-effective and equitable manner.

The stated objective of the deferrals policy is to deliver savings to the Health budget in order to facilitate the return of the Government's budget to surplus by 2013. However, it is difficult to reconcile this apparent objective with the medicines which have been selected for deferral. The deferred medicines include a number of drugs which are targeted towards relatively niche patient populations as well as listings which have been predicted to result in savings to Government. As such, it is unlikely that deferring these listings will to contribute in a meaningful way to returning the Budget to surplus. Thus, the willingness of the Government to adopt such a policy, despite its potential to deliver worse health outcomes for patients at increased costs, strikes all concerned Stakeholders as ill-conceived and grossly unproductive.

b) Any consequences for patients of such deferrals

The deferral of Symbicort® (budesonide/eformoterol) for chronic obstructive pulmonary disease (COPD) has negative consequences for patients with respect to both health outcomes and costs, with no discernable impact on reducing the Budget deficit. Rather, by deciding to defer the listing of Symbicort® for COPD, the Government has forgone the anticipated savings that the listing is predicted to generate.

Impact of the deferral on health outcomes

The deferral of the PBS listing of Symbicort® represents a missed opportunity for patients to benefit from the improved health outcomes delivered by faster relief of COPD symptoms and reduced steroid exposure.

COPD is a serious, progressive and disabling disease which affects nearly 1 in 5 Australians over the age of 40.[1] It is a major cause of disability, hospital admission and premature death and is the 5th greatest contributor to the overall burden of disease in Australia.[2] Relative to other health disorders, COPD is more common in any year than the most common types of cancer, road traffic accidents, heart disease or diabetes and in terms of financial and total (i.e. including the burden of disease) costs per case, is more costly than cardiovascular disease, osteoporosis, hearing loss or arthritis.[1]

Although incurable, proper management of COPD, including appropriate use of medication, presents the best opportunity to reduce the overall impact of COPD and stem or slow disease progression.[1] The role of fixed dose combinations of an inhaled corticosteroid (ICS) and long-acting β_2-agonist (LABA), such as Symbicort®, in the treatment of COPD is well established. Combination therapy has been shown to result in clinically meaningful improvements in quality of life, a reduction in symptoms and a reduction of acute exacerbations of the disease. Exacerbations of COPD often result in hospitalisation and are associated with poor prognosis and increased mortality.[2]

In her press release of February 28th, 2011, the Minister for Health announced that PBS listing for a number of medicines (including Symbicort® for COPD) which had received a positive recommendation following consideration at the November 2010 meeting of the

[1] Access Economics Pty Ltd (2008). Economic impact of COPD and cost effective solutions
[2] The Australian Lung Foundation and the Thoracic Society of Australia and New Zealand (2009). The COPDX Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease

PBAC, would be deferred. One of the reasons provided to support the deferrals was the availability of PBS-listed treatments which could serve as alternatives for the deferred medicines. It was not made clear to AstraZeneca what the Minister considered to be the currently listed alternative to Symbicort® for patients with COPD. We can therefore only assume that the alternative identified for Symbicort® was Seretide® (fluticasone/salmeterol), which is the only ICS/LABA fixed dose combination currently PBS-listed for the treatment of COPD. There are however, key differences in the properties of the specific ICS and LABA monocomponents included in Symbicort® and Seretide® respectively, which have the potential to adversely impact on patient outcomes. As such, it is inappropriate to consider these agents as equivalent alternatives.

Differences in steroid load and the impact on adverse events

Symbicort® provides the lowest registered daily dose of ICS in a fixed dose combination for the treatment of COPD. This is significant because many of the side effects associated with ICS therapy, such as immunosuppression and osteoporosis, are dose-related. The product information for Seretide® recommends that patients who are at a greater risk of adverse effects related to ICS may require a reduced dose; however the devices which can deliver this reduced dose are currently only PBS-listed for the treatment of asthma.[3] As such, there is currently no reimbursed therapy available for patients with COPD who require a lower dose of Seretide® to mitigate against the risk of ICS-related adverse effects. There is no requirement to decrease the dose of Symbicort® in patients who are at a greater risk of ICS-related adverse effects. Therefore, Symbicort® represents an important option for those patients with COPD who need to reduce the dose of ICS used to manage their illness.

Differences in time to onset of relief from COPD symptoms

COPD is characterised by breathlessness which in the early stages of the disease occurs on exertion but as the disease progresses gradually becomes worse, to the point where it interferes with the activities of day-to-day living such as getting dressed or leaving the house. Given their significantly reduced lung function (very severe patients can have lung function which is less than 30% of normal), patients with COPD need fast relief from breathlessness. With Symbicort®, patients will feel the effects within 5 minutes. Seretide® has a slower onset of action and as such, it takes 15-20 minutes before the drug reaches its full effect. The

[3] GlaxoSmithKline 2011). Seretide® Accuhaler® and MDI product information. Accessed via the following URL on 15/07/2011:http://www.pbs.gov.au/pbs/pdf-viewer?pdf=%2Fmeds%2Fpi%2Fgwpserti10408.pdf

product information for Seretide® specifically states that it is not for relief of acute symptoms for which a fast and short-acting inhaled bronchodilator (e.g. Ventolin®) is required.[3] As such, patients treated with Seretide® may need to resort to increasing their use of medicines such as Ventolin® to manage their breathlessness. Thus, Symbicort® provides faster relief from the symptoms of COPD and allows patients to better manage their breathlessness without have to resort to the use of additional medicines.

Impact of the deferral on cost to patients

COPD imposes significant financial stress on sufferers and their families. The deferral of the PBS listing of Symbicort® for COPD represents a missed opportunity to ease the financial burden on sufferers by reducing their medication costs.

Each pack of Seretide® contains sufficient doses to provide for one month's worth of therapy for COPD. In contrast, each pack of Symbicort® contains sufficient doses to provide for two month's worth of therapy for COPD. Thus, over the period of a year, a patient receiving Symbicort® for COPD will pay for 6 prescriptions (with each pack of Symbicort® lasting 2 months). By comparison, a patients receiving Seretide® for COPD will pay for 12 prescriptions (with each pack of Seretide® lasting one month). As can be seen from Table 1 below, the net result is that patients pay twice as much for treatment with Seretide® for COPD as compared to Symbicort®.

Table 1 Annual cost to patients with COPD treated with Symbicort® and Seretide® respectively

Product	Cost per prescription		Scripts/year	Annual cost to patient	
	Concessional	General		Concessional	General
Symbicort®	$5.60	$34.20	6	$33.30	$205.20
Seretide®			12	$67.20	$410.40

It should be noted that an increase in patient co-payments means that patients contribute more to the cost of their medicines. Subsequently, because a COPD patient pays less for Symbicort® (compared to Seretide®), Government pays more. This aspect was the key motivation for the decision to defer the PBS listing of Symbicort® for COPD, which suggests a preference to shifts costs from the Government to patients.

As discussed in our response to Term e below, the predicted increase in cost to Government associated with a difference in patient co-payments is more than offset by savings generated

due to lower monthly treatment costs associated with Symbicort®. Thus, the listing of Symbicort® for COPD represents a saving to Government versus the current PBS-listed alternative.

A further consideration relates to the economic vulnerability of this particular population. Patients with severe COPD often have very poor lung function, resulting in significant breathlessness and reduced ability to undertake day-to-day activities including work. Access Economics estimated that the employment rate for sufferers of COPD was almost 20% lower than that of the general population.[1] Furthermore, there is evidence which suggests that the risk of developing COPD is increased in people with a lower socioeconomic status.[1]

Given the progressive nature of the disease, treatment of COPD tends to be cumulative with more medications being required as the disease state worsens. As such, patients with COPD, particularly those with more severe disease, receive multiple medications to manage their condition. The combination of a limited income and the requirement for multiple medicines to manage their condition means that expenditure on medicines represents a significant economic burden for people with COPD. Thus, the deferral of the PBS listing of Symbicort® for COPD denies these patients the opportunity to reduce their expenditure on medications and obtain a degree of relief from the pressure that medication costs bring to bear on their limited income.

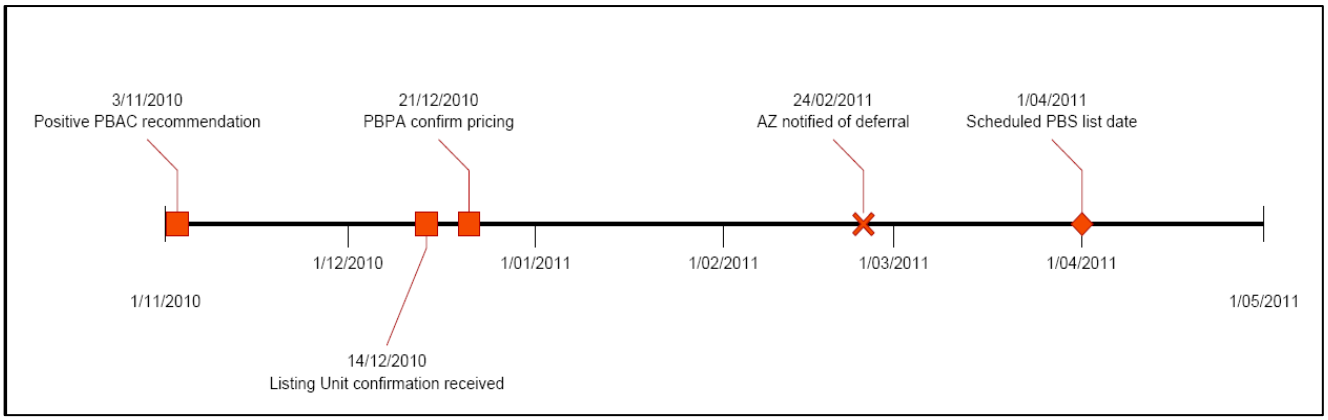
c) Any consequences for the pharmaceutical sector of such deferrals

The launch of new products or indications requires a significant investment of both human and financial resources. The lack of consultation around the deferral process and extremely late notice provided to companies of the decision to defer PBS listing introduces significant commercial uncertainty, which makes it extremely challenging to bring products to market in Australia in a timely manner without the risk of incurring substantial losses.

The PBAC issued a positive recommendation to list Symbicort® for the treatment of COPD following consideration at its November, 2010 meeting. AstraZeneca subsequently received notification of the Pharmaceutical Benefits Pricing Authority's (PBPA) acceptance of our pricing proposal for Symbicort® for the COPD indication on the 21st of December, 2010. The Listing Unit had previously confirmed (14 December, 2010) that all required documentation was in place to proceed with a 1st April 2011 listing, subject to pricing being agreed with the PBPA. On this basis, launch activities were fully underway when we received notification via

telephone on the 24th February 2011 that the listing for COPD had been deferred. Figure 1 below presents a timeline of the chain of events leading up to the notification of deferral.

Figure 1 Timeline of events leading to notification of deferral of PBS listing of Symbicort® for COPD



The launch of a new product or indication represents the culmination of more than 12 months worth of planning and requires significant investment of both human and financial resources. Companies undertake a raft of activities to ready the market for launch, including the manufacture and importation of stock to meet anticipated demand, initiation of education programmes for health care professionals and patients and sales force training. Given the significant sunk costs associated with these activities, where possible, companies try to obtain a degree of certainty regarding the anticipated date of PBS listing prior to committing resources.

In the case of Symbicort®, AstraZeneca was notified of the deferral just 4 weeks before the anticipated list date. By this stage significant investment had been undertaken to prepare for the launch of the COPD indication on the basis of positive feedback received from the PBAC, PBPA and Listing Unit of the Pharmaceutical Evaluation Branch.

The lack of consultation around the deferral process and lack of timely notification of the decision by the Government to defer PBS listing introduces significant commercial uncertainty for companies and makes it extremely challenging to plan for launch. In an effort to mitigate losses incurred as a result of Cabinet deferrals, companies may decide to wait until they have received definitive advice from the Government regarding PBS list dates before initiating launch activities, which could serve to exacerbate the delays to access that have already come to pass as a result of the implementation of the deferrals policy.

d) Any impacts on the future availability of medicines in the Australian market due to such deferrals

Australian affiliates compete with other markets to secure permission and resources to launch new products and indications. Cabinet deferrals introduce significant commercial uncertainty which may drive companies to preferentially devote resources to launching first in markets with a greater degree of policy stability. "Innovative" medicines in particular require significant investment in production infrastructure. The commercial uncertainty which accompanies the deferral policy makes it difficult for companies to prioritise investment in production capacity for the Australian market over other markets. Thus, the deferrals policy has the potential to delay access to the "innovative" medicines it is purportedly designed to support.

The PBAC enjoys a formidable reputation for rigour in assessing new medicines for Government subsidy and as such, plays a pivotal role in supporting the objective of the PBS of delivering timely access to medicines that Australians need, at a cost individuals and the community can afford. Thus, it is not surprising that news of the Government's decision to defer the PBS listing of medicines which have received a positive recommendation from the PBAC was met with concern from interested Stakeholders, not only in Australia but also abroad.

As discussed in our response to Term c above, the launch of new products or indications requires significant investment by Pharmaceutical companies of both human and financial resources. Cabinet deferrals introduce significant commercial uncertainty, particularly given the lack of consultation and clarity around the criteria used to select medicines for deferral. This uncertainty may drive companies to preferentially devote resources to launching first in markets with a greater degree of policy stability, in preference over Australia, the end result being that Australian patients will have to wait longer to access medicines than their counterparts in the other major markets.

The longer-term implications associated with this policy also warrant further consideration. The Minister has expressed a preference for funding "innovative" medicines. However, targeted therapies, biotechnology products and novel drug formulations have extremely long launch lead times. These lead times are driven by the complexity associated with the manufacturing process, which at times requires companies to invest significant resources into building dedicated facilities to produce these products.

Decisions to invest in production infrastructure are informed by forecasts provided by individual markets of anticipated launch dates and expected demand. Indeed, AstraZeneca has experience of a situation where the predicted Australian demand for a product resulted in a decision to build additional manufacturing capability. The introduction of the deferral policy makes accurate forecasting extremely challenging which makes it difficult for companies to prioritise investment in production capacity for the Australian market over markets with a greater degree of policy stability. Thus, the deferrals policy has the potential to delay access to the "innovative" medicines it is purportedly designed to support.

e) The criteria and advice used to determine medicines to be deferred

The deferrals policy is characterised by a lack of clarity regarding the criteria used to select medicines for deferral, a lack of consistency between the stated "criteria" and the medicines which have subsequently been selected for deferral and a lack of transparency regarding the source of advice used to facilitate the decision-making process.

The Minister has issued a number of statements defending the decision to implement the deferrals policy; however, there persists a lack of clarity regarding the criteria used to select medicines for deferral, a lack of consistency between the stated criteria and the medicines which have subsequently been selected for deferral and a lack of transparency regarding the source of advice used to facilitate the decision-making process.

Based on the statements put forward by the Minister, it would appear that cost to Government is one of the main criteria used to select medicines for deferral; however it is difficult to reconcile this apparent criterion with the medicines which have been selected for deferral. The deferred medicines include a number of drugs which are targeted towards relatively niche patient populations as well as listings which have been predicted to result in savings to Government. As such, it is unlikely that deferring these listings will to contribute in a meaningful way to returning the Budget to surplus.

Cost to Government

With specific reference to Symbicort®, an analysis of the cost implications associated with the proposed listing for COPD predicted savings to Government of less than $10 million during the first 5 years following PBS listing. This analysis used the prices listed in the Schedule of Pharmaceutical Benefits, known as the dispensed price per maximum quantity or DPMQ. This is the price that Pharmacists use when they claim reimbursement from the Government for each prescription that they dispense. As such, this price reflects the actual price that Government pays for each prescription (less patient co-payments).

Table 2 below presents the annual cost to Government per patient for Symbicort® and Seretide® for the treatment of COPD, based on the DPMQ. Although the DPMQ for Symbicort® is higher than the DPMQ for Seretide®, because each pack of Symbicort® provides for 2 months of therapy for COPD compared to one month for each pack of Seretide®, the monthly treatment costs for Symbicort® are lower, hence the predicted savings to Government of listing Symbicort® for COPD.

Table 2 Annual cost to Government for Symbicort® and Seretide® for COPD

Product	DPMQ	Cost/year	Annual cost to patient		Annual cost to Govt	
			General	Concession	General	Concession
Symbicort®	$91.01*	$546.06	$205.20	$33.60	$340.86	$512.46
Seretide®	$78.67	$944.04	$410.40	$67.20	$533.64	$876.84

*DPMQ approved by PBPA which would be included in the Schedule of Pharmaceutical Benefits following listing of COPD indication

AstraZeneca believe that the decision to defer the listing of Symbicort® for COPD is based on a misunderstanding of costs associated with the listing (please refer to our response to Term f of the Inquiry for further information). As such, we stand by the conclusion supported by the analysis presented in Table 2 above which demonstrates that PBS listing of Symbicort® for COPD will result in savings to Government.

Preferential funding of "life-saving" medicines

The Minister has expressed a preference for funding what are deemed to be "life-saving" drugs. However, this implies that a trade-off has been made between patients with conditions such as COPD and bipolar disorder which, while not immediately life-threatening result in significant morbidity and reduced quality of life, versus those whose conditions are imminently fatal. As stated by the Chair of the PBAC, the Committee aims to "purchase health outcomes rather than purchase products". In doing so, the Committee hopes to achieve the maximal health benefit for the Australian population from the finite funds available for healthcare, in the face of competing budgetary priorities. Therefore, the PBAC considers the comparative impact of a medicine on both the quality and quantity of additional life gained versus currently available therapies, prior to making a recommendation to list the product.

The success of the PBAC is achieving this balance is supported by data which demonstrates that Australians do better in terms of key health indicators than the majority of their OECD counterparts whilst spending a significantly lower proportion of GDP on health. Thus, by overriding the recommendations made by its own Expert Committee, the Government risks undermining the very system which is recognised throughout the world as a model for delivering optimal health outcomes in a cost-effective and equitable manner.

Medicines which were deferred were not "innovative" and have PBS listed alternatives

Finally, the Minister has justified the deferral of selected medicines on the basis that the deferred drugs are "not truly innovative" and that "there are drugs already on the PBS that provide treatment for conditions, similar to those offered by the deferred drugs." With respect to the apparent criterion around innovation, in reality there are very few medicines whose introduction has resulted in a major paradigm shift in the way the disease in question is treated. Rather, advancements in the treatment of disease have come about through a series of what could be deemed incremental innovations. A good example would be the evolution of agents used to treat major depressive disorder. Early agents such as tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs), while effective, were associated with significant toxicity. The first incremental innovation was the introduction of selective MOAIs which, while still effective, were associated a significantly reduced incidence of adverse effects and potential for drug interactions. The next incremental innovation came via the selective serotonin uptake inhibitors (SSRIs), which delivered good efficacy with

improved tolerability. The selective MOAIs could not have come about without the learnings derived from the TCAs and non-selective MAOIs and likewise the SSRIs could not have come about without the learnings derived from the agents which came before. As such, applying an arbitrary criterion around the degree of innovation that a medicine delivers to justify the deferral of PBS listing shows a complete lack of appreciation for the way in which medicines evolve over time to ultimately deliver improved health outcomes.

The basis of the claim that alternative therapies are available on the PBS for the conditions which the deferred medicines treat warrants further consideration. Given the lack of consultation with relevant Stakeholders (in particular patients and their treating healthcare professionals) prior to making the decision to defer listing (please refer to our response to Term g of the Inquiry below), it is unclear as to the source of advice used to ascertain if indeed currently listed medicines provide true alternatives to the deferred medicines. As discussed in our response to Term b of the Inquiry provided above, although both Symbicort® and Seretide® contain an ICS and LABA, differences in the properties of the specific ICS and LABA monocomponents mean that the deferral of PBS listing for Symbicort® for COPD has the potential to impact adversely on patient outcomes. Furthermore, the deferral of the PBS listing of Symbicort® for COPD will result in patients paying more for their treatment which is a significant consideration given the economic vulnerability of this particular patient population.

In summary, the deferrals policy is characterised by a lack of clarity regarding the criteria used to select medicines for deferral, a lack of consistency between the stated "criteria" and the medicines which have subsequently been selected for deferral and a lack of transparency regarding the source of advice used to facilitate the decision-making process.

f) The financial impact on the Commonwealth budget of deferring the listing of medicines

The deferral of the listing of Symbicort® for COPD represents a missed opportunity for the Government to accrue savings to the PBS while delivering improved health outcomes for patients at a reduced cost to patients.

Numerous requests have been made of the Government to provide information regarding the impact of the deferrals on the stated objective of returning the Budget to surplus by 2013. To date no information has been provided.

As the analysis presented previously in Table 2 (please refer to our response to Term e on page 10) demonstrates, PBS listing of Symbicort® for COPD is predicted to result in savings to Government in the order of less than $10 million over the first 5 years of listing. In taking the decision to defer the listing of Symbicort® for COPD, the Government has forgone the anticipated savings that the listing is predicted to generate.

AstraZeneca believe that the decision to defer PBS listing of Symbicort® for COPD was based on a misunderstanding of costs associated with the listing. We trust that the following information will help to provide some clarification around this issue.

Seretide® is currently listed for both asthma and COPD. The price for asthma is different to the price for COPD and as such, the DPMQ is a weighted price which reflects the proportion of use which accrues to each indication (e.g. 90% asthma price + 10% COPD price = DPMQ). The price for Symbicort® will also be weighted following listing of the COPD indication and the weightings for asthma and COPD will be the same as those used for Seretide®.

The cost estimates which were provided to Finance and Treasury used the unweighted price for COPD (i.e. assumes 100% COPD price). This is not the price which would appear in the Schedule, nor is it the price that Pharmacists would use to claim reimbursement from the Government for each prescription dispensed.

As can be seen from the analysis provided in Table 3 below, the unweighted COPD price for Symbicort® is less than Seretide's® price because each prescription provides sufficient therapy for 2 months and as such, attracts only one prescription dispensing fee per two months as opposed to Seretide® which attracts one prescription dispensing fee each month. What is clear is that patients treated with Seretide® for COPD pay more in terms of co-payments. This means that patients contribute more to the cost of their medicines, while Government pays less.

Table 3 Cost to Government of COPD using unweighted price (NOT the PBS list price)

Product	Unweighted COPD price per 2mths of therapy	Cost/year	Annual cost to patient		Annual cost to Govt	
			General	Concessional	General	Concessional
Symbicort®	$147.36	$884.16	$205.20	$33.60	$678.96	$850.56
Seretide®	$153.78	$922.68	$410.40	$67.20	$512.28	$855.48

The analysis, based on the unweighted COPD price, as submitted to Finance and Treasury, predicted a cash impact to Government of less than $0.5 million in year of 5 listing, which resulted entirely from a reduction in patient co-payments associated with Symbicort®. This aspect was the key motivation for the decision to defer the PBS listing of Symbicort® for COPD, which suggests a preference to shift costs from Government to patients.

AstraZeneca contends that the use of any price other than the price listed in the Schedule is inappropriate to estimate costs to Government because such prices do not reflect the price that Pharmacists would use to claim reimbursement from the Government for each prescription dispensed and as such, do not reflect what the Government pays. The analysis of the cost implications associated with the proposed listing for COPD which used the PBS list price predicted savings to Government of less than $10 million during the first 5 years following PBS listing. As such, it unclear to AstraZeneca how deferring the listing of Symbicort® for COPD serves to facilitate the Government's stated objective of generating savings from the PBS to facilitate the return of the Budget to surplus in 2013.

g) The consultation process prior to a deferral

The decision to defer PBS listing of Symbicort® for COPD took place without any consultation. AstraZeneca was notified of the decision to defer the listing just 4 weeks prior to the anticipated date of PBS listing.

AstraZeneca's experience highlights the complete absence of a consultation process around decisions to defer PBS listings. Despite receiving a) a positive recommendation from the PBAC, b) approval from the PBPA regarding pricing and c) confirmation from the Listing Unit that everything was in order to proceed to listing, we were informed of the decision to defer the listing of Symbicort® for COPD just 4 weeks out from the anticipated launch date. At no point prior to receiving this notification were we invited to comment on the proposal to defer the listing or provided with the opportunity to submit any information which may have helped to address the Government's mistaken concerns regarding anticipated costs associated with the listing.

To our knowledge, no consultation with relevant Stakeholders was undertaken to ascertain the potential impact of the decision to defer PBS listing of Symbicort® for COPD on either patients or their treating healthcare professionals. Considering that the role of the PBS is to

purchase health outcomes on behalf of the Australian public, it is concerning that the Government chose to pursue this course of action without consulting with the very parties on whose behalf it has been entrusted to act.

h) Compliance with the intent of the memorandum of Understanding signed with Medicines Australia in May 2010

Cabinet deferrals undermine the two key elements which the MoU was supposed to deliver, namely: i) a predictable PBS policy environment, ii) improved access for patients to new medicines. Thus, Cabinet deferrals are contrary to both the spirit and intent of the MoU.

Medicines Australia negotiated the terms of the Memorandum of Understanding with the Commonwealth Government in good faith. The agreement delivers significant savings and fiscal certainty to Government in return for a predictable PBS policy environment. The agreement also introduced some important regulatory reforms to improve patients' access to innovative new medicines through the PBS. As such, the recent decision to implement a policy of deferring PBS listings for medicines which have received a positive recommendation from the PBAC is contrary to the spirit and intent of the MOU. Specifically, the deferrals represent an unpredictable PBS policy environment and may lead to delayed or diminished access for patients to new medicines through the PBS.

Conclusion

Cabinet deferrals undermine the important role that the PBAC plays in supporting the objective of the PBS of delivering timely access to medicines that Australians need, at a cost individuals and the community can afford. The policy is unlikely to deliver savings of a magnitude which will have a meaningful impact on the objective of returning the Budget to surplus, while delivering worse health outcomes for patients at increased costs to patients.

The deferral of the listing of Symbicort® for COPD in particular, represents a missed opportunity for the Government to accrue savings to the PBS while delivering improved health outcomes for patients at a reduced cost to patients.

Cabinet deferrals introduce policy instability and significant commercial uncertainty which may result in delayed or diminished access to medicines for Australian patients as companies are driven to preferentially devote resources to launching first in markets with a greater degree of policy stability.

The willingness of the Government to adopt such a policy, despite its potential to deliver worse health outcomes for patients at increased costs is a cause for concern for patients, health care professionals and the pharmaceutical industry alike.

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