AstraZeneca

Senate Standing Committee on Community Affairs
Community Affairs References Committee
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RESPONSE TO Questions on Notice
'Inquiry into consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme'

At the 7 May 2010 public hearing of the above Inquiry, a number of questions were taken on notice by AstraZeneca. These questions and our responses are provided below.

Question 1 : At page CA21, ***Senator FIERRAVANTI-WELLS*** *: "...Could you please take this on notice: given the uncertainty surrounding the accepted definition of interchangeability — you heard the questioning of Medicines Australia—what do you suggest is a sound definition of 'interchangeability'?... "*

AstraZeneca refers the Committee to the Medicines Australia response to this question, provided for and on behalf of the AstraZeneca and the Industry.

Question 2 : At page CA21, ***Senator FIERRAVANTI-WELLS*** *: "...what do you consider should be a fuller, more independent analysis of all clinical evidence that should be taken into consideration when medicines have to be determined as interchangeable? "*

AstraZeneca refers the Committee to the Medicines Australia response to this question, provided for and on behalf of the AstraZeneca and the Industry.

Question3 : At page CA23, Senator Moore : ***Senator MOORE****—I would like to get some information from you on notice as to the exact cost difference of the changes in terms of the drugs in your examples. "*

The examples referred to in the Question, relate to an attachment circulated at the Committee's public hearing (attached).

Using the example of CRESTOR 10mg, a person who requires the equivalent dose of Lipitor would require 30mg of that medicine. To provide this dose would require either,
a) one tablet of 10mg and one tablet of 20mg, or
b) half of one tablet of 20mg, together with a full 20mg tablet.

Both examples provide the equivalent dose of 30mg (though any strategy involving tablet breaking is uncertain) Each example would also impose an additional copayment[1] on the patient as follows :

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[1] The current patient copayment for PBS prescriptions is $5.40 for concessional card holders, and $33.30 for general patients. These copayments are required on each dispensation of a PBS maximum quantity (usually one month supply)

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In scenario a) two copayments are required: one copayment for the 10mg tablet and one for the 20mg tablet. This means a 100% increase in patient costs.

In scenario b) 1.5 tablets are required from each pack of Lipitor 20mg. This means that a single box, which would provide one month's supply if 1 tablet daily is required, will only provide one half a month's supply. This means a 50% increase in copayments.

The increases are presented below for a General patient and a concessional patient. Also please see the original attachment, previously circulated at the Public Hearing, which is also attached below.

GENERAL patient		
Lipitor dose regimen	Monthly copayment (increase v 1tab/day)	% increase, compared to one tablet, once daily
One tablet, once daily	$33.30 (na)	--
1 X 10mg + 1X20mg	$66.60 ($33.30 increase)	100% increase
1X20mg + ½ X 20mg	$49.95* ($16.65 increase)	50% increase

* 1 X $33.30 + ½ X $33.30

CONCESSIONAL patient		
Lipitor dose regimen	Monthly copayment (increase v 1tab/day)	% increase, compared to one tablet, once daily
One tablet, once daily	$5.40 (na)	--
1 X 10mg + 1X20mg	$10.80 ($5.40 increase)	100% increase
1X20mg + ½ X 20mg	$8.10* ($2.70 increase)	50% increase

* 1 X $5.40 + ½ X $5.40

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Attachment

(hand-out previously provided at the 7 May hearing)

Atorvastatin – double copayment required to achieve equipotent doses

Rosuvastatin = Atorvastatin		**Additional** PT costs#	
		General	*Concessional*
3.3 mg = 10 mg	10		
No CRESTOR dose equivalent to lowest atorvastatin dose			
		50% Increase	
5 mg = 15 mg	10 +	*($16.65)*	*($2.70)*
10 mg = 30 mg	20 + 10	*100% Increase*	
	or	*($33.40)*	*($5.40)*
	20	*50% Increase*	
		($16.65)	*($2.70)*
20 mg = 60 mg	40 + 20	*100% Increase*	
	or	*($33.40)*	*($5.40)*
	40	*50% Increase*	
		($16.65)	*($2.70)*
40 mg = 120 mg	80 + 40	*100% Increase*	
Unapproved Lipitor dose; unproven safety profile	or	*($33.40)*	*($5.40)*
	80	*50% Increase*	
		($16.65)	*($2.70)*

 # Current copays : general = $33.30 ; concessional = $5.40

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RE AstraZeneca : Supplementary submission
'Inquiry into consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme'

At the 7 May 2010 public hearing of the above Inquiry, in response to a question from Mr Will Delaat (Medicines Australia)[2], Senator Rachel Siewert confirmed that the Committee was prepared to receive supplementary submissions following the conclusion of the Public Hearing.

AstraZeneca has reviewed the evidence given to the Committee at the 7 May Public Hearing and supports the supplementary submission provided by Medicines Australia, for and on behalf of the Industry.

Additionally, AstraZeneca submits the following responses to a number of specific statements given in evidence at the public hearing.

Consultation. *At page CA93 of the proof Hansard, the Department of Health states : "Lastly, the suggestion that there was no consultation in forming the groups is simply wrong...All affected companies and other interested people had an opportunity to comment on the proposed formation of each of these groups before a decision was made..."*

To date, AstraZeneca is the only pharmaceutical company which has been materially impacted by the creation of a therapeutic group, since the introduction of the 2007 PBS Reforms. As such, it is in a unique position to be able to comment on the consultation, or lack thereof.

AstraZeneca is concerned with the evidence, quoted above, and provided to the Committee by the Department.

The formation of the high potency statin therapeutic group was announced on Budget Night and featured in the Budget papers submitted to the Parliament, including specific reference to the new therapeutic group in the forward estimates, extending to 2012-2013. However, the decision was made well in advance of the 2009 Federal Budget and AstraZeneca was not, at any time, consulted nor provided with the opportunity to comment on the formation of the Therapeutic Group, before the decision was made.

Should the Committee require corroborative evidence in support of this statement, AstraZeneca is happy to provide this to the Committee.

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[2] At page CA12 of the Hansard

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Interchangeability *: At page CA75 of the proof Hansard, Professor Lloyd Sansom states : "That is, in commencing a patient on any one of the drugs in a therapeutic group it would make no difference in health outcomes for the vast majority of patients "*

Professor Sansom reiterates this position on page CA81 ("...it would make no difference about which drug they were commenced on...") and page CA86 ("...That means that commencing a patient on any one of the drugs in a therapeutic group would make no difference to the health outcomes for the vast majority of patients...")

In each of these statements, Professor Sansom discussed the definition of interchangeability in the context of a patient commencing on a medicine.

AstraZeneca is concerned to ensure that the Committee is made fully aware that there is another very significant cohort of patients who are not covered by the definition provided by Professor Sansom. They are in fact the group which would be immediately impacted by a therapeutic group. That is, patients already on a medication (within a therapeutic group). It is these patients who could be faced with the difficult decision of having to choose between two medications where there is a difference in price and more importantly no direct clinical alternative. In summary, it is these patients who critically, should be covered by the definition of interchangeability and who are not.

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When considering the example of Crestor and the number of people who are relevant to the PBAC's definition ("commencing patients" = 12,500 per month) and those relevant to AstraZeneca's definition (patients already on Crestor = 500,000 per month) it is clear that the vast majority of people are already on Crestor and it is this majority who are at risk, from the implementation of the Policy.

As AstraZeneca's main submission explains, the lack of interchangeability of Crestor and Lipitor is particularly pertinent, when one is confronted with the reality that there is no option for a person who is using Crestor's highest strength (40mg). That is there is no dose of any alternate statin, which is approved for safe use and which can provide the same level of cholesterol control.

As such, any definition of interchangeability which doesn't include the group of people who are already using a medicine, fails to take into account the largest and most at risk population.

Therapeutic Groups are a savings policy*. At page CA93 of the proof Hansard, the Department states "Therapeutic groups are entirely a pricing measure."*

With the clear declaration that the Therapeutic Group Premium Policy is a pricing measure (page CA93), AstraZeneca reiterates the question which it has previously posed :

In the face of significant PBS savings being delivered from both PBS Reform and the more recent measures announced in the 2010 Federal Budget, this TGP cost saving measure, is not worth the risk to patients?