The Pharmacy Guild of Australia

# Follow-up Submission

# to

# Senate

# Community Affairs Committee

# into the

# Inquiry into Consumer Access to Pharmaceutical Benefits

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**Answers to 'Questions on Notice'**

On Friday 7 May 2010 representatives from the Pharmacy Guild appeared at a public hearing to assist the Committee in its deliberations. During the public hearing the Committee asked that the Guild reply to the following questions:

1. **What is the pricing implication for patients of changing from rosuvastatin to atorvastatin to achieve equipotent doses as shown in the paper tabled by AstraZeneca at the hearing?**

The respective patient copayments for rosuvastatin and atorvastatin are as follows:

| Item | Form | Strength | General Patient Copayment | Concession Patient Copayment |
|---|---|---|---|---|
| Rosuvastatin | Tablet | 5 mg | $33.30 | $5.40 |
| | Tablet | 10 mg | $33.30 | $5.40 |
| | Tablet | 20 mg | $33.30 | $5.40 |
| | Tablet | 40 mg | $33.30 | $5.40 |
| | | | | |
| Atorvastatin | Tablet | 10 mg | $33.30 | $5.40 |
| | Tablet | 20 mg | $33.30 | $5.40 |
| | Tablet | 40 mg | $33.30 | $5.40 |
| | Tablet | 80 mg | $33.30 | $5.40 |

As the Guild stated at the Public Hearing when prescribing any medicine a doctor would consult the Therapeutic Goods Administration-approved Product Information for guidance on dosages.

An extract from the rosuvastatin Product Information states:

Prior to initiating rosuvastatin, the patient should be placed on a standard cholesterol lowering diet.
The recommended starting dose is 5 or 10 mg once/day both in statin naive patients and in those switched from another HMG-CoA reductase inhibitor.

The choice of starting dose should take into account the individual patient's cholesterol level and future cardiovascular risk as well as the potential risk for adverse reactions. A dose adjustment can be made after four weeks of therapy where necessary.

The usual maximum dose of rosuvastatin is 20 mg once/day.

A dose of 40 mg once/day should only be considered in patients who are still at high cardiovascular risk after their response to a dose of 20 mg once/day is assessed. This may particularly apply to patients with familial hypercholesterolaemia. It is recommended that the 40 mg dose is used only in patients in whom regular follow up is planned. A dose of 40 mg must not be exceeded in any patient taking rosuvastatin. Specialist supervision should be considered when the dose is titrated to 40 mg.

The extract from the atorvastatin Product Information states:

Atorvastatin can be administered within the dosage range of 10 to 80 mg/day as a single daily dose.

Therapy should be individualised according to the target lipid levels, the recommended goal of therapy and the patient's response.

After initiation and/or upon titration of atorvastatin, lipid levels should be re-analysed within four weeks and dosage adjusted according to the patient's response.

Primary hypercholesterolaemia and mixed dyslipidaemia: The majority of patients are controlled with atorvastatin 10 mg once a day. A therapeutic response is evident within two weeks, and the maximum response is usually achieved within four weeks.

The dosing relativity stated in the Pharmaceutical Benefits Advisory Committee (PBAC) recommendation is not used by clinicians to initiate therapy or transfer patients from one drug to another. The Product Information is used for clinical decision making whereas the dosing relativity, as determined by the PBAC when making a recommendation to list a medicine on the PBS, is used by the Pharmaceutical Benefits Pricing Authority (PBPA) to calculate a price for the medicine[1].

As the rosuvastatin Product Information notes **"the recommended starting dose is 5 to 10 mg once a day both in statin naïve patients and those switched from another HMG-CoA reductase inhibitor"** so it is inappropriate to claim a prescriber would switch a patient from atorvastatin to rosuvastatin (or from rosuvastatin to atorvastatin) using a dose relativity of 1:3. The flow chart presented to the Committee at the hearing does not reflect clinical practice and would appear to be based on a misunderstanding of "interchangeability at the patient level" and "dose relativity" as used by the PBAC and the PBPA. This chart attempts to illustrate situations that do not exist in clinical practice and therefore the Guild believes it is inappropriate to calculate the costs to the patient using this chart.

According to the rosuvastatin Public Summary Document from the July 2006 PBAC meeting the Committee noted a meta-analysis of 29 trials that supported the claim that rosuvastatin gave rise to a statistically significantly larger percentage reduction in LDL-C than twice the strength of atorvastatin and that there was no statistically significant difference between rosuvastatin and four times the atorvastatin strength. This analysis suggested that the rosuvastatin:atrovastatin equivalent dose ratio was greater than 1:2 but less than 1:4.

The PBAC recommended listing on a cost-minimisation basis with atorvastatin, with the ratio of equi-effective doses being rosuvastatin to atorvastatin 1:3. The Guild understands that this is not information intended for the use by clinicians in treating their patients but is used by the PBPA in calculating the price of rosuvastatin to ensure that the commonwealth pays the same price for a similar outcome whether a patient is prescribed one drug or the other. In addition it should be noted that the dose relativity can change due to the Weighted Average Monthly Treatment Cost (WAMTC) process that takes into account different usage practices in the market place compared with the formal clinical trial situation. Using sample data on prescribing behaviours and best available data on script volumes for each drug, a weighted average daily (and thus monthly) cost of treatment per patient can be estimated. As an example, if drug A is listed on a cost minimisation basis versus drug B with 45 mg = 60 mg, but as used in clinical practice the average daily doses are 47 mg and 59 mg then the price for drug A should be lower and for drug B higher than based on the 45 mg = 60 mg comparison.

[1] Page 10 WEIGHTED AVERAGE MONTHLY TREATMENT COST (WAMTC) USERS' MANUAL APRIL 2009

## 2. What is the Guild's preferred definition of interchangeability?

The Guild notes the definition of Therapeutic Groups in the Weighted Average Monthly Treatment Cost (WAMTC) Users' Manual[2] is:

"Based on the therapeutic grouping policy introduced in the 1997-98 budget, a therapeutic group is a narrowly defined therapeutic sub-group where the drugs concerned are of similar safety, efficacy and health outcomes, and interchangeable on an individual patient level. The Australian Government subsidises drugs within a therapeutic group to the level of the lowest priced drug in the group, with pricing based on WAMTC methodology. Suppliers of other drugs in the therapeutic group are able to set prices above the price of the lowest priced drug with the patient paying the TGP which is the price difference between the lowest priced drug and the drug prescribed."

The Guild is confident that the PBAC has the necessary expertise to interpret "interchangeability" to ensure that that the Australian Government subsidises drugs within a therapeutic group to the level of the lowest priced drug in that group to ensure that the taxpayer obtains value for money. The savings obtained using this pricing methodology guarantee the long term sustainability of the PBS and enable the subsidy of new medicines for other therapeutic areas or patient groups currently unable to access the medicines they require.

The Guild suggests that it may be worthwhile for the Department's Publishing, Industry Liaison and Listing Section (PILLS) to offer regular seminars to industry personnel to increase the understanding of pricing policies used by the Department.

## 3. To what extent is the market for bisphosphonates genericised?

Using information provided at www.pbs.gov.au the extent to which the market for bisphosphonates has been affected by generics can be estimated. The website[3] shows the 12.5% price reductions that have been applied legislatively, administratively and partially following the listing of a generic. The following bisphosphonates included in this are:

Statutory 12.5% reductions

| Drug | Manner of Administration | Date of Effect |
|---|---|---|
| Alendronic Acid | Oral | 1 December 2007 |
| Etidronic acid and calcium | Oral | 1 August 2005 |

Partial 12.5% reductions

| Drug | Manner of Administration | Date of Effect |
|---|---|---|
| Alendronic Acid with Colecalciferol | Oral | 1 December 2007 – applied to alendronic acid component |

## Summary

The Guild would reiterate that it supports the concept of Therapeutic Groups and the WAMTC methodology as effective mechanisms to achieve value for money without affecting patient outcomes. The Guild notes that the savings made as a result of these policies ensure that the PBS remains sustainable and the Australian taxpayer has timely access to the medicines they need, at a cost individuals and the community can afford.

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/1C5B91CD91180B33CA25732B0048D60F/$File/WAMTC-manual-April2009.pdf

[3] http://www.pbs.gov.au/html/pdf/industry/Pricing_Matters/Pricing_of_PBS_Items/PRICE%20REDUCTIONS%2020100401