19 May 2015

Dr Suzanne Hill
Chair, Pharmaceutical Benefits Advisory Committee

Dear Dr Hill,

We are writing to you in response to recent reports that the government is considering delisting over the counter (OTC) medications from the PBS and advice from the office of the Minister for Health that this decision would be made by the PBAC. We wish to raise our concerns about the financial impact this decision may have on concessional patients with chronic musculoskeletal pain, especially osteoarthritis (OA), and on quality of care. Our main concerns relate to paracetamol.

Over 80% of PBS scripts for paracetamol are for the ‘osteo’ slow release formulation, available as a restricted benefit for the relief of persistent pain associated with OA (Item 8814X). Usage is in accord with local clinical practice guidelines that currently recommend paracetamol as first line pharmacological therapy for this condition.¹

Costs to concessional patients

The rationale for delisting OTC medications such as paracetamol presented by the Minister in her media statements has been that these medications can be purchased more cheaply from supermarkets and other suppliers. While this may be the case for general patients, our research suggests that, without a PBS script, concessional patients are unlikely to be able to purchase paracetamol more cheaply in equivalent quantities and will be financially disadvantaged.

Paracetamol scripts on the PBS for OA supply either three packs of 100 x 500mg tablets or two packs of 96 x 665 mg modified release tablets (paracetamol osteo), providing around one month’s supply per script. Some online or discount pharmacies may be able to provide this quantity of generic 500mg paracetamol tablets for around the same price as the co-payment, although shipping costs can add substantially to the cost. However, the minimum price we have been able to find for this quantity of generic paracetamol osteo was $7.98² through an online discount chemist (excluding shipping fees of $6.90). This is 31% higher than the concessional co-payment of $6.10, and more than double the cost if shipping fees are considered. The osteo formulation is only available from pharmacies.

Not everyone has access to a cut price pharmacy, especially in rural and remote areas, or feels comfortable with online purchases. Older, less mobile people also tend to be limited in their capacity to shop around. As a result, many concessional patients are likely to continue to buy their paracetamol from the same pharmacy where they get their other medications and would be paying the often higher prices they charge. A spot check of three pharmacies in Sydney this week found the osteo formulation selling from $5.99 - 9.95/ pack, or at a total cost of $11.98-19.90 for the equivalent quantity available on a PBS script. For generic 500mg paracetamol, the costs per pack were $2.99-6.50, so the overall cost for 3 packs available on a PBS script would be $8.97-$19.50.

¹ Royal Australian College of General Practitioners (RACGP) Clinical guidelines for the non-surgical management of osteoarthritis 2009
Many people with arthritis and chronic pain already struggle with the costs of doctor’s visits, medications, supplements and other services they need to manage with their condition, and are unable to absorb additional costs that may seem minor to others.

**Delisting may drive demand to other PBS subsidised therapies with poorer safety profiles**

The increased costs concessional patients are likely to face if paracetamol is delisted create an incentive for them to seek, and GPs to prescribe, the next line PBS-listed therapies for OA, such as non-steroidal anti-inflammatory (NSAIDs) or opioids. These therapies are associated with far less favourable safety profiles than paracetamol, especially for people with co-morbid conditions.

This shift in prescribing patterns is likely to reduce any savings to the PBS from delisting paracetamol and may even increase costs to both the PBS and the health system if more expensive products with greater side effects are prescribed. The Industry Commission in a 1996 report on the pharmaceutical industry noted that paracetamol was once delisted from the PBS, but this led to a shift to more expensive drugs, so it was relisted within 12 months.3

**Efficacy and safety considerations should drive decisions relating to PBS listing of paracetamol**

Increasingly, evidence suggests there is a need to review current clinical recommendations for the use of paracetamol in the management of OA because of safety and efficacy questions. Paracetamol is associated with liver toxicity and with an increased risk of cardiovascular, gastrointestinal and renal disease,4 although these adverse effects occur less frequently than with NSAIDs and opioids. More recently a review suggests limited clinical benefit in the management of OA.5

However, any changes in management need to be based on clinical recommendations and consensus rather than on the potential to achieve cost savings. Consequently, we have recommended to the Minister for Health that a formal review of the current clinical practice guidelines for the use of paracetamol in OA be conducted before any decision is taken regarding its status on the PBS.

**Access to other effective treatments may reduce pharmaceutical costs for OA**

Strategies such as weight loss, strengthening exercise and pain management techniques have benefits comparable to medication6 but with fewer side-effects for people with OA and may also delay disease progression. These interventions currently receive little support through the health system, limiting their uptake. Better health system support for these strategies offers significant potential to reduce reliance on pharmacological and surgical treatments – and costs - for OA management.

In conclusion we urge the PBAC not to make any decision to change the PBS listing of paracetamol until a formal review of the current clinical practice guidelines for its use in OA is complete and consideration is given to how other effective management strategies for OA can be put in place.

Yours sincerely

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President
Australian Rheumatology Association

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