

15 February 2010

## Proposal to apply reference pricing across different brands of risperidone

PHARMAC is seeking feedback on a proposal to apply reference pricing across different brands of risperidone from 1 June 2010, where such reference pricing is possible in light of the contractual arrangements PHARMAC has with the different suppliers.

In summary, this proposal would result in the subsidy for the Ridal brand of risperidone tablets being reduced to the level of the subsidy for Apo-Risperidone tablets and Dr Reddy's Risperidone tablets from 1 June 2010.

All other currently funded brands of risperidone tablets (Apo-Risperidone, Dr Reddy's Risperidone and Risperdal) would remain fully funded. We note that Risperdal tablets have protection from subsidy reduction until 1 July 2012; therefore, no changes to the subsidy for Risperdal tablets could occur before 1 July 2012. Risperidone orally disintegrating tablets (Risperdal Quicklet) and microspheres for injection (Risperdal Consta) would also remain fully funded.

If the supplier of Ridal (Douglas Pharmaceuticals) did not reduce its price to match the new subsidy, patients could either pay a manufacturer's surcharge to remain on the Ridal brand or could switch to any other funded brand to remain on a fully funded product.

Further details of this proposal can be found on the following pages.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 5 March 2010** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

## Details of the proposal

From 1 June 2010 the subsidy for the Ridal brand of risperidone tablets would be reduced in Section B of the Pharmaceutical Schedule to the level of Apo-Risperidone and Dr Reddy's Risperidone as follows (prices and subsidies expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed subsidy
Risperidone	Tab 0.5 mg	Ridal	20	\$5.20	\$1.17
			60	\$15.60	\$3.51
Risperidone	Tab 1 mg	Ridal	60	\$30.77	\$6.00
Risperidone	Tab 2 mg	Ridal	60	\$61.53	\$11.00
Risperidone	Tab 3 mg	Ridal	60	\$92.32	\$15.00
Risperidone	Tab 4 mg	Ridal	60	\$123.05	\$20.00

Note that the proposed subsidy would apply to both the bottle and blister packs for each strength.

## Background

Risperidone is a benzisoxazole derivative antipsychotic agent. It is registered for:

- the treatment of schizophrenia and other psychotic disorders.
- the treatment and long term control of mania in bipolar disorder.
- alleviating affective symptoms (such as depression, guilt-feelings, anxiety) associated with schizophrenia and maintaining the clinical improvement during continuation therapy in patients who have shown an initial response to treatment with risperidone.
- the treatment of behavioural and psychological symptoms of dementia such as aggressiveness (verbal outburst, physical violence), activity disturbance (agitation, wandering) or psychotic symptoms.
- the treatment of conduct and other disruptive disorders in children, adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviours (e.g. aggression, impulsivity and self-injurious behaviours) are prominent.
- the treatment of autism in children and adolescents.

There are currently four fully subsidised brands of risperidone tablets: Apo-Risperidone, Dr Reddy's Risperidone, Ridal and Risperdal. Annual expenditure on risperidone is approximately \$13.4 million, approximately 30% (\$4.1 million) of which is on risperidone tablets.

The subsidy for Ridal and Risperdal tablets is currently approximately 4–6 times higher than the subsidy for Apo-Risperidone and Dr Reddy's Risperidone tablets. All brands are registered as safe and effective by Medsafe. We note that registration of the generic brands (Apo-Risperidone, Dr Reddy's Risperidone and Ridal) included the requirement to

demonstrate bioequivalence to the innovator brand (Risperdal), so we expect that patients would get the same therapeutic benefit from any of these brands.

The Pharmacology and Therapeutics Advisory Committee (PTAC) supports the application of reference pricing across brands in the risperidone market to achieve savings, which would allow investment in other areas of health need. The relevant portion of the minutes of PTAC's November 2009 meeting relating to risperidone reference pricing is copied below. Note that the minutes also mention reference pricing of quetiapine and olanzapine; however, the current proposal only relates to risperidone tablets.

### **Antipsychotic Subsidies**

The Committee noted that PHARMAC was considering applying reference pricing across different brands of atypical antipsychotics (specifically, risperidone, quetiapine and olanzapine), following patent expiry and generic entry into these markets.

The Committee noted that generic risperidone and quetiapine brands have been funded since 2007 and had gained considerable market share (38% and 22%, respectively). The Committee considered that generic entry into these markets had been relatively non-problematic, noting that up to a quarter of all patients had switched brands of these antipsychotics at least once according to PHARMAC's data.

The Committee noted that the Centre for Adverse Reactions Monitoring (CARM) had received only a small number of reports of adverse effects following a risperidone or quetiapine brand switch, and that the problems reported were of relatively minor clinical significance apart from "therapeutic response decreased".

The Committee noted that reference pricing across brands could result in some patients needing to switch brands in order to remain on a fully subsidised product (eg if the supplier of the reference priced brand did not reduce the price to match the new subsidy).

The Committee noted that Medsafe registration of generic antipsychotics included a requirement to demonstrate bioequivalence against the innovator brand, meaning that the vast majority of patients would receive the same benefit from a generic brand as from the innovator brand.

The Committee considered that, as with any brand switch, there were likely to be a small percentage of patients who would be suspicious of a different brand in these markets, which could lead to reduced compliance. The Committee considered that it was not possible to prospectively identify such patients or to define a set of clinical criteria that would capture such patients. The Committee considered that this issue would be relatively minor and no more or less manageable or problematic than brand switches in other markets. The Committee considered that it was unlikely that an extended transition period (meaning the length of time between notification and implementation of reference pricing) would make much difference to the successful implementation of reference pricing in these markets.

The Committee supported the application of reference pricing across brands in the risperidone, quetiapine and olanzapine markets as a means to achieving savings.