

27 September 2007

To clinicians, patients and caregivers

**RITALIN SR SPECIAL ACCESS SUBSIDY (methylphenidate 20 mg sustained-release tablets)**

PHARMAC has agreed to allow funding of Ritalin SR for patients who have experienced serious adverse reactions when switching from Ritalin SR to Rubifen SR, the recently funded brand of sustained release methylphenidate hydrochloride. This action is being taken in response to concerns raised by Medsafe and the Centre for Adverse Reactions Monitoring (CARM).

As PHARMAC cannot guarantee the ongoing long-term supply of Ritalin SR we would urge you to consider this mechanism only in cases where all other alternative treatment options have been unsuccessful.

A number of patients have reported serious adverse reactions associated with switching from Ritalin SR to Rubifen SR, including aggressive or threatening behaviour and, less commonly, unusual psychiatric events. These adverse reactions were reported in less than 2% of patients and did not have any obvious cause. Most of the adverse reactions reported to CARM occurred within a few days of the brand switch.

Medsafe remains satisfied that the two brands are bioequivalent, and that no safety issues have been identified for patients currently stabilised on Rubifen SR. However, Medsafe is seeking further information from the supplier of Rubifen SR, AFT Pharmaceuticals, to try and determine whether any further action is necessary.

While Medsafe conducts its investigations into Rubifen SR, PHARMAC intends to make Ritalin SR available, on application, to those patients with documented evidence of serious adverse events associated with the change from Ritalin SR to Rubifen SR.

A copy of the application form is attached to this letter. This form is also available on the PHARMAC website at [www.pharmac.govt.nz](http://www.pharmac.govt.nz). Please note that in order for applications to be processed in a timely manner it is important that details of the nominated pharmacy are completed on the application form. This must be a pharmacy that has sourced and agreed to stock Ritalin SR for patients (either from New Zealand or from overseas under Section 29 of the Medicines Act 1981).

Please call 0800 66 00 50 (9am to 4pm weekdays) if you require further information.

Yours sincerely



Dr Peter Moodie  
Medical Director