

29 June 2023

Pharmac - Te Pātaka Whaioranga
The Terrace
Wellington 6143

By email to: enquiry@pharmac.govt.nz

Tēnā koe

Re: To broaden the initial Special Authority Number for methylphenidate to include earlier access to the Ritalin LA preparations.

Introduction

Executive summary:

1. There are important clinical limitations in the successful use of currently available first-line treatment options for ADHD, particularly for young children.
2. The use of longer-acting preparations earlier in treatment is preferred by most patients and leads to significant advantages (better adherence; quicker titration which leads to service efficiencies; reduced stigma; less diversion).
3. Ritalin LA addresses many of the limitations of current first-line treatments and now has a favourable cost-benefit ratio as a first-line treatment.

The NZ Faculty of Child and Adolescent has been very pleased with the increase in access to a range of ADHD medications in recent years. This includes Pharmac's decisions to no longer require a Special Authority Number (SAN) for atomoxetine and the decision to fund the introduction of the low cost Teva ER Methylphenidate ER (available with the initial application for a methylphenidate SAN). We also note that Pharmac has been successful in achieving significant savings in relation to Concerta and Ritalin LA which were previously relatively expensive preparations, particularly Concerta. However, we are very concerned that there has been a massive increase in demand over recent years for both the diagnosis and treatment of ADHD in young people, largely due to increases in community awareness of ADHD and more efficient referral pathways. This has translated into most regions having very long waitlists for the treatment of young people with this disorder. While it is not under our remit, we also note that access to assessment and treatment for adults within the public sector is extremely poor.

At present Ritalin LA preparations are only available on a second SAN application (alongside Concerta) for those young people where there is a significant risk of diversion or where immediate release methylphenidate has been ineffective due to administrative or compliance difficulties. **We seek earlier access to the relatively inexpensive Ritalin LA preparations while preserving the relatively expensive Concerta for those situations stipulated as at present.**

There are several rationales for this application.

Firstly, the recent position statement from the Canadian Paediatric Society (2018) state that **“extended-release preparations are recommended as first-line treatments for most children and youth with ADHD”**.¹ This is due to a range of factors including significant improvements in adherence. The position statement notes that the titration period for finding the right dose and preparation of methylphenidate is quicker for those who have been initially trialled on an extended-release preparation. This would lead to significant efficiencies and cost savings to NZ mental health and paediatric services and would have a positive effect on waiting lists. Other publications indicate that most providers will initiate once daily extended-release preparations such as Concerta or Ritalin LA in older children and adolescents if they have the option.^{2,3} Alongside this, discreet choice experiments find that most parents prefer long-acting over immediate release preparations.⁴

Second, **extended-release preparations have important pharmacokinetic advantages over immediate release and sustained release preparations** in many situations. They lead to lower peak serum concentrations and tend to avoid troughs in serum levels in comparison to immediate release preparations (see figure 1). This results in a lower adverse effect burden and extends the action of the medication. We note that Rubifen SR 20mg and Teva ER Methylphenidate are available on the first authority number. These medications are not ideal for many younger children. Rubifen SR 20mg is widely known as having a relatively short duration of action (very often 5-6 hours) which does not sufficiently cover the school day, necessitating top-up doses of methylphenidate in the early afternoon. These are not generally required with Ritalin LA. Teva ER Methylphenidate is generally less effective for primary school age children who require higher plasma levels of methylphenidate in the morning when they are more likely to be undertaking challenging core academic subjects (see figure 1) and because appetite suppression often continues for an extended.

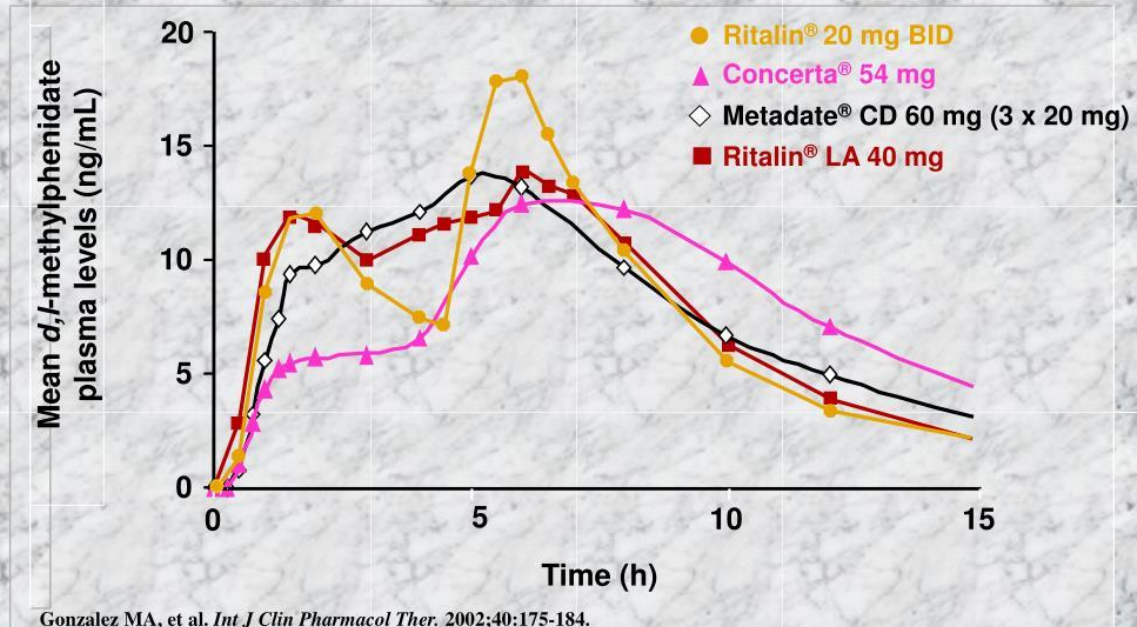
Third, extended-release preparations **reduce stigma** for young people. Most young people have strong preference for long-acting medications and object to the need to take immediate release preparations at school at lunchtime. This increases peers’ awareness of their ADHD and contributes to bullying (which is already known to be considerably more likely in those with ADHD than others).

Fourth, extended-release preparations are much **less likely than immediate release preparations to be diverted** for a range of purposes.⁵ The lack of availability of medication at school reduces diversion to fellow students. It is also much easier for parents, adolescents and others to divert methylphenidate when they have access to greater numbers of pills.

Fifth, **existing first-line sustained and extended-release treatment options (Rubifen SR 20mg and Teva ER 18mg preparations) are not available in low doses** and are not able to be tolerated by many very young people to be a first -line treatment. This is also often the case when additional medical conditions (failure to thrive; low weight) or mental health (anxiety; autism; tic disorders) conditions are present. Rubifen SR20mg is very difficult to titrate when individuals do not tolerate 20mg increments. The Ritalin LA 10mg dose is particularly useful in these situations.

Sixth, we note that the **Ritalin LA preparations are now much cheaper** than they were some years ago. They are now only marginally more expensive than the Teva Methylphenidate preparations, although they remain considerably cheaper than Concerta (which has also come down a lot in price over the years).

Comparison of Extended-release Methylphenidate Dosage Forms



N.B. There will remain some young people for whom commencing with an extended-release preparation is less desirable. This is often the case for very young children where the adverse effect burden at the start of treatment is quite likely to be too great, even with Ritalin LA 10mg. For these individuals, continued initial use of low dose methylphenidate (doses of 2.5-5mg) is often indicated. We also note that Teva ER Methylphenidate will often be the initial preparation of choice for older adolescents and adults who do not have significant substance use issues due to its extended duration of action.

We hope you view this application favourably. Please do not hesitate to contact us at nzoffice@ranzcp.org if you require any further information.

Nāku noa, nā

J. F. Gregson

Dr John Gregson
Chair, New Zealand branch of the Faculty of Child and Adolescent Psychiatry
(RANZCP)

References

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