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Baclofen – Feedback on proposal to delist 1mg/ml proprietary product

Thank you for the opportunity to comment on the proposal to delist the proprietary baclofen 1mg/ml liquid. Earlier this year the Pharmacist and Therapeutics SIG of the Paediatric Society provided a survey showing which hospitals used the proprietary 1mg/ml liquid or those who manufactured the national standardised 10mg/ml suspension. We also highlighted a myriad of errors noted individually and via MERP when different strengths are dispensed. This highlighted the need for one strength.

With Pharmac proposing to delist the 1mg/ml liquid, we should in theory only have the 10mg/ml standardised formula available. Recent discussions have shown that many community pharmacies are manufacturing a 1mg/ml strength. This is information that we have only been made aware of recently.

The following to be noted:

- Prescribers and families prefer the 1mg/ml strength due to safety concerns over the higher strength.
- Children usually start on low doses and prescribers often titrate using mL leading to errors when a different strength is dispensed
- Anecdotally, the 10mg/ml suspension is a very thick suspension which is often not manufactured by community pharmacies. As a thick suspension, it is hard to measure accurate dose adjustments eg 0.1ml
- Community pharmacies manufacture a 1mg/ml suspension, albeit one that is not nationally tested.

As paediatric pharmacists, we strongly advocate for one strength to decrease errors. We also would ask for the proprietary product to be funded. This is best practice and with such a product currently available, this would be our preferred option. Although the product is not currently registered in New Zealand, it is a similar situation to many other products on Section 29 which Pharmac currently fund eg: Micelle E (with special authority), ethambutol, selegilene to name a few. These products are funded on Section H and Section B and we would strongly ask that the Baclofen 1mg/ml liquid is considered for similar funding. This is due to errors occurring with two strengths available. There will be more errors with this high-risk medicine whilst we have two strengths available.

Recommendation:

- We recommend NOT delisting Baclofen 1mg/ml
- We would encourage applying similar criteria to this proprietary product to allow use in the community as well as hospital to reduce the risk of errors with two strengths being available.
- We would encourage a universally funded and available proprietary product of 1mg/ml strength
- We should look at manufacturing a 1mg/ml strength, with stability testing, and could liaise with the national extemporaneous compounded group to prioritise this. This would be so that a compounded product could be available should the proprietary product ever be in short supply.

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Supported by members of the P&T SIG