# THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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Submission re Therapeutics Products Bill
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Thank you for the opportunity to comment on the Therapeutics Products Bill. On behalf of the Pharmacists and Therapeutics SIG of the Paediatric Society of NZ, I am contacting you regarding our concerns about some of the proposed changes.

**Off-label use of medicines**
We are concerned that the application of a SCNSA for any off-label use of medicine will not be appropriate in many situations especially in hospital settings.
Individual SCNSA will be a very high administrative burden in many circumstances (for example paediatrics). Current practice is that off-label use is predominantly governed by guidelines. CDHB has recently developed policy to cover these situations.
Off –label example: omeprazole datasheet informs dosing from age 1 year. Omeprazole is often used in infants for GORD – is this an example of off-label use and would SCNSA be required for every use of this? Another example is sildenafil which has guidelines and Special Authority approval for use in pulmonary hypertension however the datasheet states 'not for use in children' for the tablets which are used to manufacture a liquid.

**Out of stock**
When products are out of stock, a recent example magnesium sulphate injection, we are able to obtain continued supplies by contacting overseas suppliers and bringing stock in under section 29. The TPB aims to stop this. This could cause serious problems in some of our most vulnerable patients.

## Comments on the TPB Information Session:

***Slide 8 Product approval requirements*** *–generally a TP can't be imported or supplied unless it is approved. Exceptions are:*
*•the Regulator can declare some classes of product to be approval-exempt*
*•the import &/or supply of an unapproved product for a specific patient via a 'special clinical needs supply authority'*
*•a licence or permit or regulation can authorise the import &/or supply of an unapproved product (eg for a clinical trial).*

We have situations where a product eg recent magnesium sulphate injection, is unavailable from the supplier. We are currently able to order alternative stock from other overseas suppliers to ensure continuous supply of critical medicines. We need to ensure this process can continue for medicines used in hospitals. However, there also needs to be consideration to the use of these unregistered medicines and the need for SCNSA which would be very difficult to monitor for out-of-stock situations when the product is usually available.

***Slide 34 The requirements would tighten access to unapproved medicines***
*The supply of an unapproved therapeutic product would require a 'special clinical needs supply authority' to ensure there is an active & recorded consideration of why an approved medicine is not appropriate*
*As the 'off-label' use of a medicine is outside of its approval, a SCNSA would be required. However, there would be minimal requirements (eg, it could be a tick box on the prescription)*

In paediatric and neonatal medicine, we often prescribe doses according to established local and international guidelines when the medicine's datasheet does not give dosing for children eg omeprazole in infants, sildenafil for pulmonary hypertension. In these instances, it would be hard to manage applying/approving SCNSA documentation for all cases. If a medicine is being used for a medical condition that has no guidance around dosing and is truly 'off-label' then a SCNSA is appropriate but there are so many situations where medicines are used off label and many prescribers are unaware because the clinical guidelines for their use are so well-known.
The intended process for an unregistered medicine is OK but not for intended off-label use (of a registered product).

***Slide 34 continued:*** *Who can issue a SCNSA will be set via the Bill and Regulations. It is intended that:*

- *Health practitioner prescribers could issue SCNSA for the off-label use of approved medicines*
- *Only medical Practitioners could issue a SCNSA for medicines that have not been approved in New Zealand (as is the case currently). But once a SCNSA had been issued for a particular patient for a particular medicine, a health practitioner prescriber could prescribe that patient's ongoing supply.*

We agree with this but only when a medicine really needs a SCNSA as mentioned above.

If possible, we would also like more understanding of the proposed process for SCNSA and to have the opportunity to provide comment/input into the development of this process to help ensure its workability in the clinical setting. I am happy to be contacted for further comment on proposed changes that impact paediatric and neonatal prescribing.

Yours sincerely

Louise McDermott
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