No 380

House of Representatives

Supplementary Order Paper

Tuesday, 18 July 2023

Therapeutic Products Bill

Proposed amendment

Brooke van Velden, in Committee, to move the following amendment:

Clause 120

After *clause 120(2)* (page 90, after line 27), insert:

(2A) For the purposes of **subsection (2)(c)**, the Regulator may rely on a report, assessment, or decision made by, or information received from, an entity designated under **section 346** to establish reasonable grounds for the purposes of that subsection.

Explanatory note

This Supplementary Order Paper amends the Therapeutic Products Bill. As the circumstances which justify a product being made available in New Zealand through provisional authorisation may include a public health emergency or other time critical matter, it is essential for the avoidance of doubt that the Act clearly states the Regulator may rely on evidence from trusted overseas entities or expert organisations when determining a product's safety, quality, and efficacy. Any uncertainty in this regard presents a risk of delay or a trigger for debate concerning what evidence a decision may be based on, and delay and debate may be counter-productive given the circumstances. The proposed change makes it explicit that trusted overseas evidence may be considered reasonable grounds for the Regulator to make a decision for provisional authorisation, and therefore mitigates the risks of delay and debate that would arise with insufficiently clear legislation.

Wellington, New Zealand:
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