

House of Representatives

Supplementary Order Paper

Tuesday, 18 July 2023

Therapeutic Products Bill

Proposed amendments

Dr Shane Reti, in Committee, to move the following amendments:

Clause 122

Replace *clause 122(2)* (page 91, line 36 to page 92, line 5) with:

- (2) A market authorisation is complete when the applicant has provided all information required by the rules made for the purposes of **section 364**.

Delete *clause 122(3)* (page 92, lines 6 to 8).

Clause 123

Replace *clause 123* (page 92, lines 12 to 30) with:

123 Issue of market authorisation for NHP

- (1) The Regulator must issue a market authorisation for an NHP of the kind sought to the person named in the application as the proposed sponsor if—
 - (a) the product meets the criteria for a market authorisation of an NHP in **section 124**; and
 - (b) the proposed sponsor meets the criteria for being the sponsor of an NHP in **section 125**.
- (2) For the purpose of **subsection (1)**, the Regulator must accept the applicant's declaration referred to in **section 124** as sufficient evidence of the matters declared unless there is evidence to the contrary.

- (3) If a Crown organisation is to be the sponsor, the market authorisation must be issued to the Crown organisation in its own name (and not to the Crown).

Clause 124

In *clause 124(1)*, replace the words before *paragraph (a)* (page 92, lines 32 and 33) with “An NHP meets the criteria for a market authorisation if the sponsor declares that all of the following apply:”.

Delete *clause 124(2)* (page 93, lines 13 to 16).

Explanatory note

This Supplementary Order Paper amends the Therapeutic Products Bill. Under the bill, natural health products (NHP) will require market authorisation. Information and statements around the self identifying mechanism of market authorisation are not only unclear, but in some cases contradictory. There are also concerns with the capacity of the regulator to moderate a potentially huge number of NHP authorisations. This SOP effectively develops functional “notification” instead of “authorisation” by maintaining the market authorisation framework for NHPs but has the authorised criteria, the sponsor criteria and the applicants declaration all accepted by default. In this respect the legislation will function more like the near unanimous cross party support for the previous Natural Health and Supplementary Products Bill (NHSPB) 324-2.