No 385

House of Representatives

Supplementary Order Paper

Tuesday, 18 July 2023

Therapeutic Products Bill

Proposed amendments to SOP No 368

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

Clause 148

In *clause 148*, replace the definition of **protected active ingredient information** with:

> **protected active ingredient information** is information that—
>
> (a) is given to the Regulator in an innovative medicine application or in relation to a licence or permit application under this Act; and
>
> (b) is not in the public domain when the application is made

In *clause 148*, replace the new definition of **protection period** with:

> **protection period**, in relation to protected active ingredient information, means a period referred to in **section 149(2)** that applies to the information.

Clause 149

Replace the heading to *clause 149* with "**Protection of active ingredient information from disclosure or use**".

Replace *clause 149(1)* with:

> (1) The Regulator must not use or disclose protected active ingredient information, except—
>
> (a) in accordance with **section 150**; or
>
> (b) after the expiry of the protection periods outlined in **section 149(2)** but only for the purposes of determining whether to issue any other market authorisation.

In *clause 149(2)*, after "for the medicine's protected active ingredient information", insert "under **subsection (1)(b)**".

Clause 150

Replace *clause 150* with:

150 Limited circumstances in which protected active ingredient information may be disclosed or used

The Regulator may disclose or use protected active ingredient information during a protection period for the information if the disclosure or use is for the purpose of the Regulator performing their functions or exercising their powers under this Act and—

(a) the regulations allow the disclosure or use; or

(b) the applicant (or, if a market authorisation has been issued, the sponsor) agrees in writing to the disclosure or use; or

(c) the information has entered the public domain and is therefore no longer confidential.

Explanatory note

This Supplementary Order Paper (SOP) amends the data protection provisions of the Therapeutic Products Bill. One of the most commercially valuable assets owned by pharmaceutical companies is confidential information (including technical data and trade secrets) and intellectual property relating to new or innovative medicines. This information and intellectual property is commercially sensitive and valuable, and pharmaceutical companies invest heavily in protecting it from loss and disclosure. Whether or not the regulation in a prospective market will provide sufficient protection of their commercially sensitive information is a critical commercial consideration for pharmaceutical companies in deciding whether to supply new medicines into that market. Markets that have insufficient protections in place run the risk of being perceived as high risk and of pharmaceutical companies choosing not to sell their medicines there. This is particularly true of small markets like New Zealand, where the financial return on the introduction of a medicine may be relatively limited. One of the guiding principles of the Therapeutic Products Bill is that the regulation of therapeutic products should support innovation and the timely availability and choice of therapeutic products. This is to ensure that New Zealand has an innovative, robust health and biotechnology sector to support its community and is compatible with its trading partners. The data protection provisions of the Bill, as currently drafted, however, provide less protection than those currently provided under the Medicines Act 1981 and may deter pharmaceutical companies from selling innovative medicines here. If that occurs, then consumers may face a significant reduction in the range of medicines (especially new ones) available to them. This will not support a well-functioning market for therapeutic products and runs contrary to the Bill's stated aims. This risk was clearly signalled to the Health Select Committee by multiple industry

submitters. US, Europe and other leading innovation economies also grant additional protections beyond the baseline RDP (in this case, 5 years) that can apply to new indications that require new clinical data. In the US, there is a +3 year per indication protection for small molecules and in Europe there is a +1 "per molecule" protection for certain new indications. The amendments proposed to the Bill in this SOP address several key deficiencies in the drafting of the Bill's data protection provisions. First, the current provisions only protect information relating to the active moiety of a medicine, which is a small portion of the commercially sensitive information relating to a new or innovative medicine. The Bill currently allows the remainder of the information to be used and disclosed with limited restrictions. The amendments in this SOP seek to ensure that the full range of such commercially sensitive information (including trade secrets relating to the manufacturing process undertaken to produce innovative medicines) is protected. Secondly, the current provisions do not provide protection of confidential information for a long enough period. The amendments in this SOP seek to protect such information against disclosure so long as it remains confidential. The amendments also protect against unfair commercial use of that information by permitting the regulator to use this information for the purpose of assessing applications for approvals of third-party products only after the protection periods have expired. These provisions increase the degree of confidence that suppliers of innovative therapeutic products can have in participation in the New Zealand market by reducing the likelihood that the New Zealand market presents undue risk to intellectual property and commercially sensitive information. Appropriate data protection provisions are also important for New Zealand's domestic health and biotechnology sector, as well as ensuring that New Zealand does not fall behind with its major trading partners and promoting New Zealand as a market for innovation consistent with the Bill's guiding principles.

Wellington, New Zealand:
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