No 384

House of Representatives

Supplementary Order Paper

Tuesday, 18 July 2023

Therapeutic Products Bill

Proposed amendments to SOP No 368

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

Clause 7

In *clause 7(3)(a)*, after "market authorisation", insert "and market notification".

Clause 9

In *clause 9(1)*, after "market authorisations", insert "and market notifications".

In *clause 9(2)*, replace "a medicine, a medical device, or an NHP" with "a medicine or a medical device".

Delete *clause 9(3)(c)* .

Clause 10

In *clause 10(1)*, after "market authorisation", insert "or market notification".

Clause 12

In *clause 12(2)*, after "market authorisation", insert "or market notification".

Clause 13

Replace *clause 13(2)* with:

(2) The Regulator is responsible for—

(a) issuing market notifications; and

(b) receiving market notifications; and

(c) granting licences and permits.

Clause 14

In *clause 14*, definition of **market authorisation**, delete "**or 123**".

In *clause 14*, after the definition of **market authorisation**, insert:

> **market notification** means a notification received by the Regulator for an NHP under **section 138B**

In *clause 14*, replace the definition of **sponsor** with:

> **sponsor**,—
>
> (a) in relation to a medicine or a medical device with a market authorisation, means—
>
> (i) the person to whom the market authorisation was issued under **section 118**; or
>
> (ii) if the market authorisation has been transferred under **section 130**, the person to whom it was transferred; or
>
> (iii) in **Part 7 or 8**, a person who is taken to be the sponsor under **section 202 or 238** respectively; and
>
> (b) in relation to an NHP with a market notification, the person who gave the market notification to the Regulator under **section 138B**

Clause 61

In the *heading to clause 61*, delete "**, permitted health benefit claim,**".

Delete *clause 61(2) and new subsections (3) and (3A)*.

Clause 62

Delete *clause 62(2A) and (2B)*.

Clause 67

Replace *clause 67(3)(a)* with:

> (a) the NHP has a market notification; or

In *clause 67(4)(a)*, replace "standard authorisation or an export authorisation" with "market notification".

Clause 68

In *clause 68*, replace "a medicine, a medical device, or an NHP with a standard authorisation or provisional authorisation" with "a medicine or a medical device with a standard authorisation or provisional authorisation, or an NHP with a market notification,".

New clause 110A

In *new clause 110A(2)*, replace "market authorisation" with "market notification".

In *new clause 110A(3)*, replace "market authorisation" with "market notification".

In *new clause 110A(4)(a)*, replace "market authorisation" with "market notification".

In *new clause 110A(4)(b)*, replace "market authorisation" with "market notification".

Clause 111

In *clause 111(2)*, replace "market authorisation" with "market notification".

New clause 111A

In the *heading to new clause 111A*, replace "**market authorisation**" with "**market notification**".

In *new clause 111A(2)*, replace "market authorisation" with "market notification".

In *new clause 111A(4)*, replace "standard authorisation" with "market notification".

Clause 112

In *clause 112(2)*, replace "standard authorisation or provisional authorisation" with "market notification".

Clause 113

In the *cross-heading above clause 113*, after "*market authorisation*", insert "*or market notification*".

Replace *clause 113(2)(a)* with:

> (a) the market authorisation for a medicine or medical device or the market notification for an NHP (**product A**) ceases to be in force; and

In *clause 113(4)(a)*, after "market authorisation", insert "or market notification".

In *clause 113(6)*, after "market authorisation", insert "or market notification".

Clause 114

Replace *clause 114(2)(a)* with:

> (a) a major change is made to a medicine or medical device with a market authorisation or to an NHP with a market notification (the **original product**) and the changed product is released into the supply chain without a market authorisation or market notification; and

In *clause 114(4)(a)*, after "market authorisation", insert "or market notification".

In *clause 114(6)*, after "market authorisation", insert "or market notification".

Part 4

Replace the *heading to Part 4* with "**Market authorisations for medicines and medical devices, and market notifications for NHPs**".

Clause 117

In *clause 117(1)(a)*, replace "a medicine, a medical device, or an NHP" with "a medicine or a medical device".

In *clause 117(1)(c)*, replace "a medicine, a medical device, or an NHP" with "a medicine or a medical device".

Replace *clause 117(2)* with:

(2) An authorisation for a medicine or a medical device is issued by the Regulator under **section 118**.

Clauses 122 to 125

Delete *clauses 122 to 125 and the cross-heading above clause 122*.

Clause 126

In *clause 126(1)(a)*, replace "a medicine, a medical device, or an NHP" with "a medicine or a medical device".

Delete *clause 126(1)(h)*.

Clause 129

Delete *clause 129(1)(a)(iii)*.

Clause 136

Delete *clause 136(c)*.

New subpart 1A of Part 4

After *clause 138*, insert:

Subpart 1A—Market notifications for NHPs

138A Market notification for NHPs

A **market notification** accepted by the Regulator authorises an NHP for import, supply, and export on an ongoing basis.

138B Submission of market notification for NHP

(1) A person in New Zealand may submit to the Regulator a market notification for an NHP.

(2) A market notification for an NHP is complete when the person has provided all information required by rules made for the purposes of **section 364**.

138C Receiving market notification for NHP

(1) The Regulator must accept a market notification for an NHP of the kind sought to the person named in the notification as the proposed sponsor if—

(a) the product meets the criteria for a market notification of an NHP in **section 138D**; and

(b) the proposed sponsor meets the criteria for being the sponsor of an NHP in **section 138E**.

(2) For the purpose of **subsection (1)**, the Regulator must accept the applicant's declaration referred to in **section 138D** 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 notification must be submitted by the Crown organisation in its own name (and not to the Crown).

138D Criteria for market notification for NHP

An NHP meets the criteria for a market notification if the sponsor declares that the product conforms to the following criteria:

(a) the NHP ingredients in the product are all recognised NHP ingredients:

(b) there is reasonable and adequate evidence to demonstrate the safety and quality of the NHP:

(c) the NHP will meet any product standards that apply to it:

(d) any custom health benefit claim that the sponsor proposes to make about the NHP is substantiated in accordance with **section 61(4) and (5)**:

(e) if the application is for an export authorisation, the NHP will meet any export standards that apply to it:

(f) the NHP is not a prohibited product:

(g) any other criteria in the rules are met.

138E Criteria for sponsor of NHP

(1) A person meets the criteria for being the sponsor of an NHP if the Regulator is satisfied on reasonable grounds that all of the following apply:

(a) the person is—

(i) an individual who is ordinarily resident in New Zealand; or

(ii) a body corporate that is incorporated in New Zealand; or

(iii) the Crown or a Crown organisation:

(b) the person does, or proposes to do, any of the following activities (other than on behalf of another person who meets the criteria in **paragraph (a)**):

(i) import the NHP or arrange for another person to do so:

(ii) manufacture the NHP in New Zealand for supply or export or arrange for another person to do so:

(iii) export the NHP or arrange for another person to do so:

(c) the person is, or will be, able to comply with their obligations under this Act:

(d) the person consents to being the sponsor of the NHP:

(e) the person is a fit and proper person to be the sponsor of an NHP.

(2) For a person who is not the responsible manufacturer of the product to be able to meet the criterion in **subsection (1)(c)**, the person must have a contractual relationship with the responsible manufacturer that the Regulator is satisfied on reasonable grounds—

(a) will enable the person to comply with their obligations under this Act:

(b) meets any criteria in the rules about the nature of the contractual relationship and the matters that must be agreed.

138F Market authorisation provisions apply to market notifications

Sections 126 to 138 apply to a market notification as if it were a market authorisation (with any necessary modifications).

Clause 192

In *clause 192(1)*, replace "market authorisation" with "market notification" in each place.

In *clause 192(2)*, replace "market authorisation" with "market notification".

Clause 194

In *clause 194(1)(a)(i)*, after "provisional authorisation", insert "or market notification".

In *clause 194(1)(a)(ii)*, after "market authorisation", insert "or market notification".

In *clause 194(2A)(a)*, after "market authorisation", insert "or market notification".

In *clause 194(2A)(aa)*, replace "market authorisation" with "market notification".

Clause 202

In the *heading to clause 202*, after "**market authorisation**", insert "**or market notification**".

In *clause 202(1)*, after "market authorisation", insert "or market notification".

In *clause 202(2)*, after "market authorisation", insert "or market notification".

Clause 203

In *clause 203(1)*, after "that have a market authorisation", insert "or market notification".

In *clause 203(1)*, replace "do not have a market authorisation" with "do not have a market notification".

Clause 234

In *clause 234(1)(a)(ii)*, after "market authorisation", insert "or market notification".

Clause 235

In *clause 235(1)(a)(ii)*, after "market authorisation", insert "or market notification".

Clause 238

In the *heading to clause 238*, after "**market authorisation**", insert "**or market notification**".

In *clause 238(1)*, after "market authorisation", insert "or market notification".

In *clause 238(2)*, after "market authorisation", insert "or market notification".

Clause 253

In *clause 253(1)(b)(i)*, after "export authorisation", insert "or a market notification".

Clause 325

In the *heading to clause 325*, after "**market authorisation**", insert "**or market notification**".

In *clause 325(2)(a)*, after "market authorisation", insert "or market notification".

In *clause 325(2)(b)*, after "market authorisation", insert "or market notification".

Clause 332

After *clause 332(1)(a)(i)*, insert:

(ia) accepting market notifications; and

Clause 363

In *clause 363(2)(a)(i)*, after "market authorisation", insert "or market notification".

In *clause 363(2)(a)(iii)*, after "market authorisation", insert "or market notification".

In *clause 363(2)(a)(iv)*, after "market authorisation", insert "or market notification".

Clause 364

In *clause 364(1)*, after "apply to an application", insert "or notification".

In *clause 364(2)(a)*, after "application", insert "or notification".

In *clause 364(2)(c)*, after "application", insert "or notification".

In *clause 364(3)*, after "application", insert "or notification".

Schedule 1

In the *heading to clause 12 of Schedule 1*, replace "**market authorisation**" with "**market notification**".

In *clause 12(2) of Schedule 1*, replace "market authorisation" with "market notification".

In *clause 12(3) of Schedule 1*, replace "market authorisation" with "market notification".

In *clause 12(3)(a) of Schedule 1*, replace "market authorisation" with "market notification".

In the *guidance note below clause 12 of Schedule 1*, replace "market authorisation" with "market notification".

Schedule 3

In *Schedule 3*, delete the item relating to section 123.

Explanatory note

This Supplementary Order Paper amends the Therapeutic Products Bill to remove the requirements for Natural Health Products (NHPs) to be authorised and instead replaces it with a notification regime. Under the Bill, NHPs will require market authorisation. Information and statements around the mechanism of market authorisation for NHPs are not only unclear but in some cases contradictory. Furthermore, there are concerns with the capacity of the Regulator to assess a potentially huge number of NHP authorisations. The process for NHPs should be a market notification process where the Regulator is satisfied that an NHP meets the criteria through a self-declaration process where the sponsor declares that the NHP product conforms to the relevant criteria. Currently, under *clause 124* of the Bill, an NHP would meet the criteria if the Regulator is satisfied on reasonable grounds that a number of criteria apply. This includes that there is reasonable and adequate evidence to demonstrate the safety and quality of the NHP. "Reasonable grounds" should not be a condition, because the product will be declared to meet the requirements in regulations and rules. This Supplementary Order Paper implements a notification mechanism for NHPs that is more consistent with the Natural Health Products Bill (324-2).

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