

House of Representatives

Supplementary Order Paper

July 2023

Therapeutic Products Bill

Proposed amendment

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

Clause 19 amended

In *clause 19(1)* (page 32, line 31), after "**section 16(1)**", insert "**and section 26(1)**".

Clause 26 amended

Delete *clause 26(1)* (page 36, lines 16 to 18) and insert the following:

- (1) **Software as a medical device** means software without any associated hardware (other than an unrelated device that is needed solely to present a user interface) that —
- (a) is intended for use in, on, or in relation to humans for 1 or more of the therapeutic purposes set out in **sections 15(a) to (h)**; or
 - (b) that regulations referred to in **section 19(1)** says is software as a medical device."

Explanatory note

This Supplementary Order Paper (**SOP**) amends the definition of Software as a Medical Device (SaMD) in section 26(1) the Therapeutic Products Bill 2022.

The wording of the current definition of SaMD is too broad and captures software products that have non-therapeutic purposes (for example, software used to manage patient records). This position is inconsistent with the intention of the Bill as described by Manatū Hauora Ministry of Health.

The [Manatū Hauora Ministry of Health Departmental Report to the Health Select Committee Appendix 2: Clause-by-clause analysis report dated 6 April 2023](#) states the following:

"The Bill does not intend to regulate software only with mechanical functions (e.g., used to drive or control motors and pumps of an infusion pump to pump medication out) as a standalone medical device or used for administrative purposes (eg, data transmission from hardware devices or workflow management)" (page 39)

"Additionally, the software that facilitates the provision of patient care for non-therapeutic purposes, including those for productivity, communication, finance, and education, would not be considered SaMD" (page 40)

In addition, the Ministry recommended an amendment to clause 26 *"to clarify that on (sic) the policy intention is not to capture nontherapeutic uses of software as SaMD"* (page 40).

The [Health Select Committee Report on the Bill](#) indicates that the Committee also recognised the distinction between software that has a true therapeutic purpose, and software that *"does not treat, prevent, or alleviate medical conditions, injuries, and diseases; nor does it sustain life, or investigate physiological processes"* and poses a low risk of harm to patients, but appears to have overlooked making the amendment recommended by the Ministry (page 5).

The amendment set out in this SOP narrows the scope of the software that is regulated as SaMD and is consistent with the intention of the Bill as described by the Ministry. Under the amended definition, only software that is used for one or more of the therapeutic purposes set out in clause 15 (a) to (h) of the Bill (and meets the other criteria of clause 26(1)) would be SaMD. The relevant therapeutic purposes are:

- a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury
- b) influencing, inhibiting, or modifying a human physiological process
- c) testing the susceptibility of humans to a disease or an ailment
- d) influencing, controlling, or preventing human conception
- e) testing for human pregnancy
- f) investigating, replacing, modifying, or supporting part of a human's anatomy
- g) investigating a human physiological process
- h) supporting or sustaining human life.

The amendment set out in this SOP would ensure that software that does **not** have one of the purposes listed above would **not** be considered SaMD, and therefore would not be regulated, under the Bill.

Notably, the amendment set out in this SOP does not affect the definition of "therapeutic purposes" and "therapeutic product" in the Bill, which means that the Bill continues to cover all the non-software products that it covers now (i.e., medicines, medical devices, active pharmaceutical ingredients, and natural health products). The amendment also aligns with international best practices such as the Therapeutic Goods Administration, Australia.