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13th May 2020

Commenting letter regarding **"Consultation: Scope of regulated** software-**based products" (released on** 25 March, 2020)

Dear Ladies and Gentlemen,

We refer to the published document **"Consultation: Scope of regulated** software-**based products"** which was released for consultation on Wednesday, 25 March 2020 and opened for comments among others from industry groups. We hereby submit our proposal, which we believe falls within the scope of the consultation. We, as Fresenius Medical Care, appreciate the opportunity to contribute in the development of these regulations. As a leading medical device and services company worldwide, we are submitting this letter to emphasize the pointers highlighted below, in order to welcome the proposed regulatory framework.

I. What kind of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

We support the proposed software exclusion/exemption, where adequate alternative mechanisms of oversight exist with regards to Clinical Decision Support Software, especially when:

- '(…) it is intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

- it is intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient'[i]

We see it as a crucial aspect, to exempt the mentioned type of Clinical Decision Support Software (CDSS) where the software is solely intended to be used by medical personnel, due to the fact that the mentioned type of CDSS does not formulate any prescription autonomously or give any mandatory treatment regimens. The suggestions must be in turn validated by a physician, who makes the ultimate decision when prescribing on whether to apply the proposed recommendation (predictions). Having a 'medical-personnel-in-the-**loop'** approach, the physicians are required to evaluate case-by-case whether the proposed predictions are safe for the patient.

II. What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

We propose those software-based products to be excluded from regulation by the TGA which are listed in the 'Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)- Based Software as a Medical Device (SaMD)' provided by the U.S. Food & Drug Administration as so-called 'non-device CDSS', especially where the software-based product '(...) provides certain, limited clinical decision support...[ii]'.

Furthermore, we propose to further take additional exclusion criteria into consideration and refer to *table 1* of the 'Guidance Document: Software as a Medical Device (SaMD): Definition and Classification' provided by 'HEALTH CANADA' (see Appendix A) which could serve as an additional extension of the already provided definition in the Australian Therapeutic Goods Act of software-based products that are not considered to be a medical device due to its intended purpose.

III. Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?

We propose to take the beforementioned 'Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)- Based Software as a Medical Device (SaMD)' provided by the U.S. Food & Drug Administration into consideration when informing the Australian approach to this issue.

We remain at your disposal should TGA have any query. For further clarification, please contact:

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Thank you.

With kind regards,
Fresenius Medical Care

Antony Rayment
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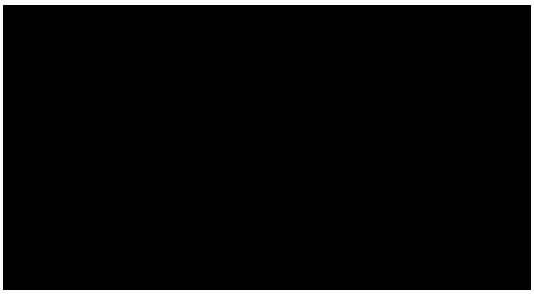

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Appendix A

Table 1: Software exclusion
Please note: software must meet all the following four criteria in order to be excluded

	Exclusion Criteria	Classification
1	Software that is not intended to acquire, process, or analyze a medical image or a signal from an IVDD or a pattern/signal from a signal acquisition system.	• Software that acquires images and data from medical devices solely for the purpose of display, storage, transfer or format conversion is commonly referred to as Medical Device Data Systems (MDDS) software, which does not qualify as a medical device. • Information from in vitro diagnostic devices (IVDDs) includes qualitative and quantitative outputs and signals from instruments, tests and assays.
2	Software that is intended to display, analyze, or print medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies, or recommendations).	• Software that matches medical information to reference information routinely used in clinical practice or self-care would meet this criterion. This could include software that matches patient symptoms and test results with best practice treatment guidelines for common illnesses. • Software that provides a reference for health care professionals to identify possible drug interactions in order to prevent adverse drug events could be interpreted to prevent an abnormal physical state as per the medical device definition. However, Health Canada does not intend to regulate this type of software since the alert provided by the software functions as a convenient mechanism for health care professionals to match patient-specific information with reference information that is readily available to the medical community and routinely used in clinical practice.
3	Software that is only intended to support a health care professional, patient or non healthcare professional caregiver in making decisions about prevention,	• Generally, software intended to inform clinical/patient management can be interpreted to fit this criterion. Informing clinical/patient management infers that the information provided by the software will not trigger an immediate or near term action.

	diagnosis, or treatment of a disease or condition.	• Software that is used to treat, diagnose or drive clinical management does not generally fit under this criterion. Treatment or diagnosis infers that the information provided by the SaMD will be used to take an immediate or near term action.
4	Software that is not intended to replace the clinical judgement of a health care professional to make a clinical diagnosis or treatment decision regarding an individual patient.	• The intended user should have access to the basis for the software's recommendation, so the user can independently review and rely on their own judgement and reach a recommendation without primarily relying on the software function. For example, software intended to provide a convenient way to perform various simple medical calculations, which are routinely used in clinical practice, would meet the fourth criterion as the software retains functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators, and is able to be independently validated. • The software should enable health care professionals, patients or non-healthcare professional caregivers to independently review the basis for the recommendations presented by the software.

Source: Health Canada (2019)[iii]

[i] Australian Therapeutic Goods Administration (TGA) (2020). Consultation: Scope of Regulated Software based products. (Link: https://www.tga.gov.au/sites/default/files/consultation-scope-of-regulated-software-based-products-march-2020.pdf , retrieved on May 8, 2020), p. 16.

[ii] U.S. Food & Drug Administration (2019). Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)- Based Software as a Medical Device (SaMD). (Link: https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf , retrieved on May 8, 2020), p. 4.

[iii] Health Canada (2019). Guidance Document. Software as a Medical Device (SaMD): Definition and Classification). (Link: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document/software-medical-device-guidance-document.pdf , retrieved on May 8, 2020), p. 9-10.