Siemens Healthineers response to the consultation "scope of regulated software-based products" from the Australian Government's Department of Health – Therapeutic Goods Administration

Siemens Healthcare Pty Ltd is the company and local legal entity responding to this consultation, the use of "Healthineers" refers to our brand.

Siemens Healthineers welcomes the open and collaborative approach of the Australian Therapeutic Goods Administration in consulting experts and stakeholders when shaping new regulatory areas[1]. We stand by with our expertise in placing active Medical Devices on international markets, including health software[2] and Software as a Medical Device[3]. For the goal of global convergence, we especially endorse that the Australian Therapeutic Goods Administration takes reference on the recent regulatory development in the European Union with the Regulations (EU) 2017/745 on Medical Devices[4], (EU) 2017/746 on In-Vitro Diagnostic Devices[5], and Guidance 2019-11 on the Qualification and Classification of Medical Device Software[6].

Prior to directly answering TGA's questions, we would like to highlight particular areas in the consultation document that compare the Australian approach with the European one.

On page 7, TGA puts an emphasis on the differences between the EU classification rules for software, and the Australian rules. Paragraph 4 explores particular differences as following:

> *"There are some additional differences compared to the EU classification rules. The EU rules are silent on public health risk and devices that provide therapy through the provision of information so these default to Class I in the EU. Depending on the intended purpose of the software, these devices may be Class I or higher in Australia. The Australian classification rules are summarised in Table 1 with further detail provided in Appendix 2."*

The EU regulations define software as an active device[7] and by this, multiple classification rules are applicable to software, which are listed in MDR Annex VIII, section "6. Active Devices". TGA assumes software providing treatment would not be explicitly covered by the EU classification rules and thus result in a lower risk class than in Australia. We believe this assumption is an incomplete view on the diversity of the EU classification rules and see possibilities for equal risk classes in the EU and in Australia: Software that is intended for treatment of diseases can do this in more than one way:

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[1] https://www.tga.gov.au/consultation/consultation-scope-regulated-software-based-products

[2] HEALTH SOFTWARE: software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care
Note 1 to entry: HEALTH SOFTWARE fully includes what is considered software as a medical device (see rationale in A.1). Note 2 to entry: The scope of this document refers to the subset of HEALTH SOFTWARE that is intended to run on general computing platforms. (source: IEC 82304-1:2016)

[3] Software as a Medical Device: The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.(source: IMDRF/SaMD WG/N12FINAL:2014)

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746

[6] https://ec.europa.eu/docsroom/documents/37581

[7] As per Article 2(4) of Regulation (EU) 2017/745 – MDR

- Software can provide information to a user for treatment. In this scenario, rule 11 applies.
- Software can initiate treatment. In this scenario, the software would be falling either under the same class as the treatment device[8] or in the highest risk class[9].
- Software can provide treatment by utilizing general purpose hardware, such as a mobile phone, to provide treatment. In this scenario, the software could be considered as active therapeutic device intended to administer energy (audio / visuals) and rule 9 applies.

Paragraph 5 continues this exploration on personalized medical devices:

> *"As part of the personalised medical device reforms, changes were also made to an existing classification rule to cover medical devices intended for creating virtual anatomical models (see Appendix 2). This is also not currently addressed in the EU medical device classification rules and so these devices would default to Class I in the EU but may be a higher classification in Australia."*

We believe the EU classification rules have descended from the GHTF/IMDRF risk-based approach and by this are in most cases agnostic to the technology utilized and focus on the risk associated with the intended purpose of the medical device in question[10]. When assuming TGA considers virtual anatomical models as aid in taking decisions with therapeutic or diagnostic purposes, they do not default to class I, but would be considered by Rule 11 a), thus being Class IIa or higher.

Response to the TGA questions on software-based products

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

Siemens Healthineers believes the advancement of technology we witness today is merely the tip of the iceberg of what to expect in the future. With rapid speed in developing new technologies in mind, safeguarding humans is a core competency of health authorities worldwide. We believe exclusion from regulation cannot be performed on its entirety. Besides medical device laws, data protection laws, information security standards and product safety considerations, especially for software intended for lay users, need to be considered. Exemption of one of those laws can potentially break the chain of dependencies and orientation manufacturers have today to be able to place such products on the market.

Nevertheless, enforcement discretion could be applied on a transparent and rational risk-based factor. Implying when other regulated entities such as certified labs, or clinicians, create an environment which is effectively able to mitigate hazards coming from wrong information of a software, enforcement discretion can be applied. On the other hand, as technology evolves, in particular considering artificial intelligence, the software is more and more assessing complex associations, which, considering the resources available in healthcare, can theoretically, but not technically be mitigated by health staff anymore. This kind of software should not be allowed for enforcement discretion.

The example on lab support software that technically diagnoses a sample:

- Is the lab able to crosscheck, or ensure by manual entered thresholds, that the diagnostic evaluation is correct? If yes, then enforcement discretion should be an option.

The example of clinical decision support software (as per the U.S. 21st Century Cures act):

[8] As per implementing rule 3.3
[9] As per Rule 22
[10] MDR Annex VIII, Chapter II, implementing rule 3.1

- Is the intended user group able to follow mitigations put in by manufacturers to explicitly cross-check the results and look on published guidelines? If yes, enforcement discretion should be an option. But if users rely completely on such software to have more time at their hands to spend with patient, mitigations from manufacturers run void. This creates a new hazardous situation which allows erroneous results to be placed in the EHR of a patient and build basis for wrong decision making.

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

We are in line with TGAs understanding of software that is listed in the consultation under "software that is not a medical device under the current application of the Therapeutic Goods Act".

Please provide details of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual?

Health Software is always expected to work reliably, regardless of its regulatory status. Software utilized in information transfer can bear the risk to mix datasets from different patients. This can result in a hazardous situation of wrong information provided. This short example should provide insights, that software can bear harm, while at the same time is not regulated as medical device as this software has no specific medical purpose, such as it is intended for storing, transmitting or visualizing medical information. On the other hand, it is put into service in the healthcare environment.

The prior paragraph resembles a situation, which is successfully handled only by operators, who have a certified quality management system in place, looking on intended uses of software, risk profiles and IT security in order to face the needs of the clinical users. There is only one country known, who made this a discipline: the United Kingdom. NHS published in 2016 two standards, on software validation in use of healthcare providers, regardless of the regulatory status of this software. These Standards have been published by the NHS and are called DCB0129[11] (manufacturer) and DCB0160[12] (operator). With these standards, healthcare institutions are able to assess residual risks of any software used in the diagnostic or therapeutic supply chain and validate always the entire system.

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

Siemens Healthineers concludes in a shared responsibility. We recommend TGA to enforce necessary medical devices regulations to software-based products. In mitigating risks coming from software that is not regulated as a medical device, operators and manufacturers could work together, similar as in the United Kingdom.

In addition, we believe it is important to aid manufacturers which regulation or regulatory requirements apply. For this, guidance should be developed which aids in distinction between software regulated as medical device, and software regulated as in-vitro diagnostic device.

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[11] https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems

[12] https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems

Author of Submission :

Tobias Schreiegg,

- Siemens Healthineers Director Regulatory Affairs and
- COCIR Co-Chair of the Medical Device Focus Group / International Affairs Focus Group.
- As representing the medical device industry, Tobias has been an active co-author of the European guidelines MDCG 2019-11 and MDCG 2020-1. (tobias.schreiegg@siemens-healthineers.com)

Primary point of contact (on behalf of the sponsor):

Hoon Koh,

- Head of Regulatory Affairs and Quality Management (hoon.koh@siemens-healthineers.com)
- Siemens Healthcare Pty Ltd (TGA Client ID 62718)