13 May 2020

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Sir/Madam

Consultation: Scope of Regulated Software Based Products

Medicines Australia welcomes the opportunity to comment on the Therapeutic Goods Administration (TGA) consultation regarding the *Scope of regulated software-based products*.

Whilst Medicines Australia primarily represents the innovator medicines industry, there are multiple interfaces between the use of medicines and software in the healthcare environment. These may include: software to aid in subject identification for potential suitability for screening in clinical trials; calculators designed to determine appropriate dosing parameters for medicines; tools to calculate risk of occurrence of adverse events based on patient characteristics; medication reminders; and medication compliance aids. Software is also increasingly used to ensure optimal clinical outcomes for new medicines. Notably, there exists a Global Medical Device Nomenclature (GMDN) code specific to pharmaceutical management support software.

As a general principle, where software provides information for a therapeutic use, with that information then used by a health professional as one of many inputs in clinical decision making regarding individual patient care, the unnecessary regulatory burden on that software should be minimized. This is compared to software that directly and solely informs such a clinical decision. Medicines Australia acknowledges that the regulation of software will continue to be both a risk and principles based approached, as per the regulatory changes made on 12 December 2019 through amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations). It is important that the regulatory framework for software does not impose unnecessary burdens to sponsors of such software. The context for the uses of software (for example, whether the role of the software is to drive a clinical decision versus providing an input to support a clinical decision) are important determinants of the appropriate level of regulation.

We welcome the recognition that the evolving nature of the digital health environment has led, and may continue to lead, to confusion over what is a medical device in relation to software.

As such, we encourage TGA to provide clear identification of what software is and is not regulated as a medical device. We support TGA providing clear and explicit guidance about the boundary for software-based products.

Clarification of what is and is not in scope through the interpretation of the regulatory definition of a medical device

This section states that "analysing patient data to screen for a disease" is considered a medical device function. However, the legislative definition of medical device in the *Therapeutic Goods Act 1989* (the Act) states that a medical device is "….used for purpose of …..diagnosis, prevention, monitoring, treatment, alleviation of a disease…. injury or disability" (that is, a therapeutic use). The classification rules in the Regulations which direct that the classification of a programmable device or software to screen for a disease or condition varies depending on the severity of the disease or condition, or public health risk, potentially introduce confusion about the regulation of screening software.

The definition of software used for the purposes of screening for a disease or condition should be reworded to avoid being overly broad. We propose that the second bullet point on page 12 should be reworded to "analysing patient data to diagnose a disease". We consider that software for the purpose of analysing patient data to diagnose a disease is captured under the first bullet "Diagnosis of an individual's disease or condition". We also propose that software for the purpose of analysing patient data to screen for a disease that is subsequently diagnosed by other methods, be explicitly listed as an example of software that is not a medical device under the application of the Act.

As currently worded, applying software algorithms to electronic health record (EHR) databases to identify potential patients for a clinical trial, or to conduct observational post-market studies using EHR data, could trigger device regulations (including investigational use requirements such as inclusion on Clinical Trial Notifications). While analysing data to diagnose disease would be a device function, screening to identify potential patients who are then diagnosed via other means should not be a device function. The current wording could negatively impact patient identification for clinical trials, particularly trials of therapies for rare diseases. Screening is a function intended to identify something that needs further investigation, whereas a diagnosis would be made on the basis of a number of inputs (including clinical presentation) and would be made by the health professional.

Software that could be potentially excluded or exempted from regulation

Medicines Australia agrees that excluding or exempting software products, which meet the regulatory definition of medical devices where that software does not pose significant harm to the individual, is consistent with the TGA's overarching principle of risk-based regulation. We note that the classification rules provide differential classification of software medical devices depending on the level of risk to individual or public health, and based on whether the software provides information to an individual or a health professional. We agree that software used by a patient to monitor a condition should be excluded or exempted.

The application of exemptions or exclusions would need to be carefully considered to avoid inconsistencies. We agree that software used by a patient to monitor a condition should be excluded or exempted. We encourage TGA to consider whether this needs to be limited to only those conditions that are mild- or self-limiting, and how monitoring would be defined. Medicines Australia concurs with the suggestion that software that provides class-based analyses rather than patient specific diagnosis or management should be excluded. Class-based analyses would not constitute a therapeutic use under the Act.

Medicines Australia agrees that Clinical Decision Support (CDS) software should be excluded/exempted from regulation when the stated criteria are met. We appreciate the effort to harmonise the regulation of CDS across regions and the alignment with the EU and FDA approach. **Further, we suggest taking a similarly aligned approach to the regulation of medical mobile apps and general wellness devices (i.e. exempting or excluding these from regulation).**

Additional comments

Medicines Australia would appreciate it if TGA provided additional guidance on the appropriate use of GMDN codes for software. This would be of benefit to industry as software manufacturers are not necessarily familiar with medical device requirements in the way that traditional device manufacturers are. Also, companies primarily active in the medicines area who support software regulated as a device are similarly not experts in this area.

I would be happy to discuss or provide further comment on any aspect of our response.

Yours sincerely

Peter Komocki
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Medicines Australia