Boehringer Ingelheim welcomes the opportunity to provide comments and feedback on the questions raised within the Consultation document: Scope of regulated software-based products.

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

Both the US FDA[1,2] and Health Canada[3] provide guidance and examples where certain software which may be considered as a medical device could be excluded from regulation in the United States of America and Canada. Examples of software-based products which are provided by both jurisdictions are considered to be of low risk of harm to patients and individuals, and/or automates simple tasks, including performing simple calculations which are routinely used in clinical practice, for health care professionals.

Such software-based products should also be **EXEMPTED** from inclusion in the ARTG (see examples below from the US FDA and Health Canada):

US FDA examples of software-based products[1,2]:

1. Help patients (i.e. users) self-manage their disease or conditions without providing specific treatment or treatment suggestions
2. Automate simple tasks for health care providers.
3. Software considered as a device by pose low risk to patients
    - provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment
    - provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)
    - specifically marketed to help patients communicate with HCP by supplementing or augmenting the data or information by capturing an image for patients to convey to their HCP about potential medical conditions
    - perform simple calculations routinely used in clinical practice

Health Canada examples of software-based product[3]:

- Software that does not have a direct impact on the diagnosis, treatment, or management of an individual's disease, disorder, abnormal physical state or symptoms (e.g. a mobile app intended to monitor daily calorie intake and energy expenditure to allow an individual to self-manage their weight).
- Software intended for administrative support of a healthcare facility
- Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, video calling
- Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps
- Software intended to serve as electronic patient records or tools to allow a patient to access their personal health information.

In addition clinical decision support/patient decision support software when it meets all of the four criteria outlined below:

- 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.
- 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
- only intended to support a HCP, patient or non-HCP caregiver in making decisions about prevention, diagnosis, or treatment of a disease or condition.
- not intended to replace the clinical judgement of a HCP to make a clinical diagnosis or treatment decision regarding an individual patient.

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

In alignment with other international jurisdictions, software based products which do not meet the definition of a medical device under the Therapeutic Goods Act, as well as software based product which are intended solely for:

- Educational or general information purposes
- Displaying of recording information
- Managing data
- Enabling communication
- Encouraging a health lifestyle

should be **EXCLUDED** from regulation by the TGA.

As described earlier, both the US FDA[1,2] and Health Canada[3] provide guidance and examples where certain software which may be considered as a medical device could be excluded from regulation in the United States of America and Canada. Examples of software-based products which are provided by both jurisdictions are considered to be of low risk of harm to patients and individuals, and/or automates simple tasks, including performing simple calculations which are routinely used in clinical practice, for health care professionals.

Such software-based products as described by the US FDA and Health Canada for exclusion from regulation in their respective countries, should also be considered by the TGA to be **EXCLUDED** from TGA regulation.

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***

As per the example provided in the Consultation document of software which are part or used with hardware devices are subjected to accreditation by other national agencies (e.g. NATA – National association of testing authorities), it sounds reasonable for such situations that additional regulation from the TGA would not be necessary.

- ***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.***

Guidance as provided from the US FDA and Health Canada could be used as a basis in determining the types of software that pose no potential for significant harm to an individual. Further TGA guidance should be provided to define which specific disease / conditions are applicable (possibly the use of the restricted representations approach relating to advertising of products to the general public). In addition, the involvement of health care professionals in the decision making should be considered.

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

The available guidance from the IMDRF, the EU, Health Canada, and the US FDA should be used in determining the kinds of software based products that can be **EXCLUDED** from regulation by the TGA.

Guidance from Health Canada and the US FDA should be used in determining the kinds of software based products that can be **EXEMPTED** from inclusion in the ARTG.

In addition, TGA should develop local guidance documents (similar to those issued by other international jurisdictions) which provides clarity and examples of which software based products are regulated by the TGA or are excluded or exempted.

Both the EU and Health Canada in their respective guidance documents include assessment/flow diagram to assist in the determination if software is a medical device.

- EU Medical Devices Regulation[4] – flow diagram for determination
- Health Canada[3]– criteria assessment to determine if software is to be regulated or not

These could be used as the basis in the development of a local online assessment tools (similar to those developed for assessing medical device classification).

REFERENCES:

1) US FDA Policy for Device Software Functions and Mobile Medical Applications
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
2) US FDA Guidance: General Wellness: Policy for Low Risk Devices
https://www.fda.gov/media/90652/download
3) Health Canada - Guidance Document: Software as a Medical Device (SaMD): Definition and Classification
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html#a2.1
4) EU - Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
https://ec.europa.eu/docsroom/documents/37581