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Sydney

I am writing to submit the response to the TGA Consultation on the Scope of Regulated Software-based products released on 25 March 2020.

lzerobzero is a nascent social enterprise founded with the intension to assist businesses with finding sustainable alternatives for their software reliance in delivering core offerings to serve as a back-up in times of need. lzerobzero is yet to make a mark. lzerobzero brings software perspectives from over twenty years of my professional experience.

I am grateful to the Therapeutic Goods Administration for the opportunity to submit my responses for your consideration as below:

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

Consumer hardware that serve as the platform for the software-based product that serves a therapeutic purpose should be exempt from inclusion in the ARTG; The products are covered by the provisions of ACCC, ACMA and other state legislations.

Software products that serve a therapeutic purpose should not be exempt from inclusion in the ARTG.

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

Software products that are used in the health context but do not serve a therapeutic purpose; so they should be excluded from regulation by the TGA:

- software based product by itself or in combination with other products is used for the sole purpose of manufacturing validated design/production processes of medical devices; evidence of acceptable impact to the medical device would be validation

reports(eg. test rigs or calibration equipment used during manufacturing to recalibrate the product prior to placing in the market)

- software based products that provide the functionality which otherwise would be available from the use of stationary; evidence of functionality would be the validation reports(eg. Display of printable reports, database of health records, appointment diaries, complaint management systems, patient diaries)
- software based products that assist with communication of information related to medical devices; the information themselves are regulated as part of the device. evidence of correct reproduction would be validation reports (eg. Dedicated database or web portal of clinical manuals, promotional materials, literature supporting clinical evidence of the device, approved product training material)
- software based products that assist with the customer communication of approved devices; evidence of correct reproduction would be validation reports(eg. Product catalogue)
- software based products that facilitate computation of widely established indicators of health and established measures or thresholds to trigger physician's follow-up; evidence would be validation reports(eg. BMI calculations)

However software products such as those listed below where the risk of failure leading to human harm is not unlike those of medical devices should be regulated by the TGA. I am unaware of any other framework for adequate oversight of the kind of software products.

- the software product interfaces with human such that it can impart harm comparable to a medical device that interfaces with the humans to an equivalent extent; product characteristic would be energy imparted by the system controlled by the software product at the human-interface being equivalent to that of a regulated medical device (eg. Software used in research incorporating neural stimulation irrespective of the end-use ranging from development of AI algorithms to the development of tool benches for researchers working with humans; symptoms in affected humans could be over use of neural faculties, not unlike disproportionate ageing of different parts of the body or organ)
- the software product whose correct use by the end user is imperative for the correct functioning of other products that are medical devices; product characteristic could be recommendation of its use in the labelling/manual of the medical device(calibration software supplied to end-users for use with medical devices, sterilisers)
- the software products that are used in the application of the 3-d printing technology for making medical devices; (3-d printers intended for printing CPAP masks)

If a software product is intended to maintaining or encouraging a healthy lifestyle of a person diagnosed with a mental health issue, then it should not be exempted from inclusion in the ARTG because provision of motivational tips is contradictory to the recognition of the mental health issue as an illness and self-management may not be the best option.

Software products intended to extract data from clinical trial or patient records would be regulated as part of the appropriate approval processes for the trial. Software intended to extract data from multiple trials or patient records, should be regulated appropriately to ensure preservation of confidentiality with full regard for port-trial situations.

Additionally the higher classification for the software-products in line with EU MDR is appropriate for reasons explained below the table:

	Diagnosing/screening and/or specifying or recommending treatment/intervention for a disease or condition	
	Provides information to an individual	Provides information to a health professional
Death/severe deterioration/high public health risk	III	~~IIb~~ **III**
Serious disease or condition/otherwise harmful/moderate public health risk	IIb	~~IIa~~ **IIB**
Any other case	IIa	~~I~~ IIa

- the healthcare provider would rely on the correctness of the information in making their own diagnosis; reliance on healthcare provider as a mitigation of inadequately validated software products is unacceptable, particularly, the reason for the discrepancy in a software product is not transparent to the user. for example, if a spring loaded blower doesn't move when the child visibly blows adequately, the physician can see the spring is stiff or stuck; if a software device recommends intervention because the child's breath volume is low, the software issue will not be transparent.
- in case the software product is the only source of information, the risk of misinformation should be higher
- in case the software product is a secondary source of information, then conflict with the primary source of information deters the bandwidth of the healthcare provider in the delivery of efficient care