HCASA
Health Consumers Alliance of SA Inc

Consumers at the centre of health in South Australia

TGA Consultation: Scope of regulated software-based products

The Health Consumers Alliance of South Australia (HCASA) is the recognised voice of South Australian health consumers and a centre of excellence in consumer and community engagement and individual and systemic advocacy.

We work in partnership with health consumers and health service providers to advocate for the health care rights of consumers, carers and the community; provide evidence-based consumer representation in health legislation, policy and planning; recruit, train and support consumer advocates to participate in health design, planning, delivery and evaluation of health services, clinical governance and safety and quality performance and we train and support health professionals and service providers to work in collaborative partnerships with consumers.

HCASA supports the regulation of software-based products where their intended purpose is to facilitate and support the use of medical devices as defined in the *Therapeutic Goods Act 1989 (Appendix 1)* ie;

- Diagnosis, prevention, monitoring, treatment, alleviation of a disease, injury or disability
- Compensation for an injury or disability
- Investigation of the anatomy or of a physiological process and
- Control of conception

Where this is potential or actual risk of poor consumer use or poor performance of the software, directly resulting in poor outcomes and increased risk of mismanagement of a disease or harm resulting from this error (eg incorrect insulin dose recommended based on poor performance of blood glucose test), then this software should not be exempt and must be regulated.

HCASA acknowledges that unnecessary regulation where the software based medical device does not pose any risk to safety, should potentially exempt the software from regulation. In supporting this however, any level of regulation that increases patient safety, improved diagnosis, prevention, treatment and alleviation of disease is fundamental to ensure safe high quality care.

Given that; 1) suppliers of excluded products would not be required to report adverse events associated with their products; 2) the TGA would not be able to take regulatory action and 3) exempted products would not have to be included in the Australian Register of Therapeutic Goods, any decision to exempt a product from regulation would need to be clearly based on public safety. Such decisions should give particular consideration to risks associated with use and performance that potentially or actually could result in harm the individual or to a community - where the community of health interest, such as people with diabetes that require regular symptom monitoring and specific medicine regimen.

There are innumerable software-based products designed specifically for use by consumers, related to such things as self help, self-management, information, lifestyle and fitness etc. In determining exemption, consideration must be given to vulnerable groups including those with low health literacy, migrant communities, people with lived experience of mental illness and Aboriginal and Torres Strait Islander people who are more likely to experience health disadvantage.

Such vulnerable groups, through health disadvantage and lower health literacy, often have reduced access to health care and health practitioners to ensure accurate diagnosis, treatment and care planning. When determining exemption of a software-based product from regulation, consideration must be given to the likely consumer group/s for which the software-based product is targeted, particularly to vulnerable and at risk groups and health conditions.

Over reliance of software-based products in the absence of clear, accurate information from a health practitioner, about their health care and access to appropriate health services, may create increased risk to such users.

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