Adjunct Professor John Skerritt
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Dear Professor Skerritt

Submission to the Consultation: Scope of Regulated Software-based products

The Medical Services Advisory Committee (MSAC) welcomes the opportunity to provide the Therapeutic Goods Administration's (TGA) comments on its "Scope of regulated software-based products" paper.

MSAC is an independent non-statutory committee established by the Australian Government Minister for Health in 1998. The MSAC appraises new medical services proposed for public funding, and provides advice to Government on whether a new medical service or health technology should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence. Amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other programmes (for example, blood products or screening programmes) may also be considered by MSAC.

MSAC collaborates across other expert advisory committees to deliver these important recommendations. With the rise of pharmacogenomics and personalised medicines, MSAC's expertise is called upon to consider, with the Pharmaceutical Benefits Advisory Committee (PBAC), pathology or diagnostic tests for use with specific medicines to determine the population group for the medicines. Medical devices may also be referred to MSAC by the Prostheses List Advisory Committee (PLAC) for placement on the Prostheses List.

The TGA assesses the safety, quality, efficacy and performance of therapeutic goods for inclusion in the Australian Register of Therapeutic Goods (ARTG). Once a therapeutic good is included in the ARTG, it may be marketed for use in Australia. MSAC relies to an extent, on TGA's regulatory system and inclusion of medical devices in the ARTG as an indication of their safety, quality and performance, in that MSAC does not usually support an item for public funding unless the medical device/service or technology is included in the ARTG.

The "Scope of regulated software-based products" paper is thus relevant to the MSAC.

MSAC notes the regulatory distinction between software-based products that are regulated by TGA as a medical device and those that are intended solely for educational/guidance or general purposes (e.g. lifestyle) and not regulated by the TGA as described in the paper.

The committee notes that the TGA is seeking feedback on a number of issues. Most relevant to MSAC are the potential exemption or exclusion of certain regulated software-based products to reduce regulatory burden on manufacturers and sponsors of the products. Examples of these products include specific disease or condition management or monitoring software and software that act as enablers of, or support clinical decisions but not relied on for primary clinical or treatment decisions.

Software-based products that are being considered for exclusion or exemption by the TGA are based on the following principles:

- products that are considered not to pose significant harm to the individual (e.g. due to inappropriate use of the product)
- products that could be or are subject to other alternative oversight mechanisms already
- products where risks that are associated with the use and performance of the product may be appropriately mitigated.

The committee notes and supports the intention to align with international practice, primarily Health Canada, the EU, the US FDA and the International Medical Device Regulators Forum where appropriate.

Specific comments offered by MSAC are:

- Application of the principles stated would allow MSAC to consider with some confidence, questions about the clinical and cost effectiveness, and safety of the products under consideration. If MSAC cannot answer these questions then the product would not be recommended for funding. Therefore, MSAC encourages application of the principles with the role of MSAC as an HTA committee in mind
- Please consider how version control on software and "me-too" products will be considered. MSAC notes that payment for services is predicated on the availability and validity of software and validated pipelines (e.g. for interpretation of genomic sequencing). It is likely that evidence of compliance with quality assurance programs will need to be in place as a pre-requisite for reimbursement. Will the TGA give any consideration to the end to end – i.e. post market monitoring of software?
- Any consideration of exemption and/or exclusion should be based on the principles above and should never compromise the capacity for MSAC and others to make decisions for the safety and benefit of consumers. It is not an efficiency to lessen oversight to reduce regulatory burden when the primary driver should be consumer safety and access
- MSAC must be able to confidently make its determinations and advise the Minister. Being able to confirm listing on the ARTG is one way of doing this effectively and transparently. Other evidence, including the reasons for applying the principles above could be acceptable in some cases.
- Any existing oversight or regulatory mechanism that may be considered in the proposal in the absence of TGA's oversight ought to be publicly and readily accessible. This will enable applicants to provide the information in MSAC applications to satisfy MSAC about the safety aspects of the device/technology etc. Similarly, MSAC or other interested parties must be able to readily access the information for review.
- MSAC recommends careful consideration and legal advice obtained to provide confidence that consumer laws are sufficient and able to fill the gap if TGA does not have regulatory oversight over the excluded or exempted software-based products as described in its paper.
- Additionally, MSAC recommends ongoing monitoring and risk management must be ensured. If this cannot be achieved by other measures i.e. by applying the principles, then TGA should retain regulatory oversight.

- In MSAC's experience, consumers expect any health-related product or service (in particular one that has received public funding at any stage, in part or in whole) to have systems for ongoing monitoring, review and incident management (e.g. re an adverse event or supply/access problems) and for these systems to be transparent to the public and regulators if/as requested.
- In addition, consumers need a single point of authoritative contact to which they can report problems from their perspective and/or ask questions as part of informed consent processes.
- The retention of some aspects of TGA oversight (e.g. products should still meet relevant essential principles of safety, performance and advertising requirements and adverse events must be reported to the TGA) could address some of these consumer expectations.
- It would seem logical that software that is not implanted is not such a risk and if it has been evaluated and fulfils essential principle 12.1 re cyber security, data management/information by the relevant software/security and requirements required for development, maintenance and production, there may be no need for duplication.
- Personalised medical devices as a greater risk and greater certainty is required thus yearly reporting on individual devices and data kept for five years is not unreasonable. Such devices include pacemakers/defibrillators. Is it envisaged that this data be stored in-country?

In summary

Software has no limits in terms of potential health-related applications and regulation through a single agency can be difficult. An alternative system could complement the work of the TGA but this needs to be open, transparent, understood and information must be readily accessible. The maturity and coverage of any alternative regulation would materially influence this. MSAC recommends that:

- any steps taken must prioritise and not compromise consumer safety and access to safe health care, and
- every step must be taken to ensure access to existing information including to consumers, and to informing the monitoring and quality assurance processes of health technologies including software.

Finally, MSAC supports an efficient, risk-based, safe and effective regulation of software-based products. MSAC would not support any change that may compromise its decision-making, or reduce the confidence of consumers or clinicians to support their care, including access to consumer evidence and perspectives on the use of any software.

Thank you for the opportunity to comment.

Yours sincerely

Professor Robyn Ward

Chair

Medical Services Advisory Committee