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To whom it may concern,

Re: TGA consultation: Regulation of software, including Software as a Medical Device (SaMD)

NPS MedicineWise would like to thank the Therapeutic Goods Administration (TGA) for providing the opportunity to offer feedback on how software, including Software as a Medical Device is regulated in Australia.

NPS MedicineWise is an independent, evidence-based organisation primarily funded by the Department of Health to educate health professionals and consumers about the appropriate use of medicines and medical tests. NPS MedicineWise improves the way medicines and other medical technologies are prescribed and used in practice. We do this through behaviour change interventions, evidence-based information to support decision making, educational programs which aim to address evidence-practice gaps, and targeted health communications campaigns.

We strongly support the strengthening of the regulatory framework for medical device software in Australia but recognise that this is an extremely challenging area and that it needs to be part of a broader framework aimed at improving the quality and safety of medical devices in Australia. Government, professional bodies and the software industry have a shared responsibility to develop and support processes to improve quality and safety in Australia. For more regulation to be effective clear guidance and standards are a prerequisite.

NPS MedicineWise has long been involved in contributing to national e-health initiatives, in particular research and recommendations for improving decision support in clinical software, the incorporation of our own decision support prompts (NPS RADAR) into prescribing software and through the development of our own MedicineWise app.

Of particular relevance is the work we have undertaken to identify the most desirable software features (where feature includes functionality or other characteristic of a software system), with each of the 50 features identified then being rated for its expected impact on safety, quality and usefulness to the clinician and patient[1]. This was followed by an equally in depth study to evaluate the features in seven general practice clinical software systems to assess the degree to which those systems supported safety and quality in general practice clinical software.[2] See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3115840/ for further details.

Comments and recommendations

Systematic approach to developing criteria

[1] Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill J, Schattner P, Snowdon T. Identification of features of electronic prescribing systems to support quality and safety in primary care using a modified Delphi process. BMC Medical Informatics and Decision Making. 2010;10(1):21. doi: 10.1186/1472-6947-10-21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881675/

[2] Sweidan M, Williamson M, Reeve JF, et al. Evaluation of features to support safety and quality in general practice clinical software. *BMC Med Inform Decis Mak*. 2011;11:27. Published 2011 May 3. doi:10.1186/1472-6947-11-27. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3115840/#B7

The above process of identifying the most important features and testing systems is an approach that could be adopted as part of the regulatory process, this time with deeper involvement of key stakeholders such as the Medical Software Industry Association. We would be happy to share our learnings and discuss ways that we could support such a process.

In addition, the findings from this in-depth evaluation of general practice clinical software provide useful insights when looking at the essential principles and criteria for the regulation of software as a medical device:

- *Standards and guidance:* Standards are needed to ensure appropriate functionality and safety requirements. Ideally software that records clinical data such as diagnoses, medicines and allergies should do so in a standard coded format. This helps to facilitate one system/software being able to 'talk to' another software system and easily exchange patient data, for example with hospital systems or personal electronic health records when they become available. These are critical to maximising the potential for medical device software to speak to other software systems thereby reducing fragmentation and enhancing patient care.
- *Unfavourable and unintended effects:* Consideration needs to be given to any unfavourable effects on workflow and communications, and any unintended effects. For example, our research into e-prescribing systems found that while they could enhance the safety and quality of prescribing (by ensuring complete and legible prescription orders, improving the detection of drug allergies and by reducing medication errors and adverse reactions[3,4,5] they may introduce new types of errors[6, 7,8] and high levels of unhelpful alerts, and impact on repeat prescribing.[9]
- *Safe medicine selection processes:* Software ought to ensure that medicine selection processes are safe. In addition to drug interaction alerts, the system should provide warnings if a drug is contraindicated, the dosage regimen is potentially harmful, or if the drug is the subject of new safety advice from the TGA. Software that includes information about medicines needs to clearly differentiate between similar-named medicines during prescribing to minimise the risk of selecting the wrong drug from a list of products.
- *Intuitive, easy to use with warnings prioritised:* Software needs to be intuitive and easy to use in practice. Messages that disrupt the workflow (eg. alerts and warnings) should be limited to reduce alert fatigue and be prioritised. Information of lesser clinical importance should not interrupt the workflow. Users should be able to see the reason for the alert.
- *Evidence-based decision support:* Decision support should be based on high quality, evidence based, up-to-date evidence and guidelines and appropriate rules; it should be clear and concise, and should include details about the source and currency of the information. Wherever possible independent, evidence-based information and clinical practice guidelines should be accessible from within the software.
- *Consumer resources:* Consumer resources and reports should be presented in a user-friendly format and use appropriate language.

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[3] Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescr bing on medication errors and adverse drug events: a systematic review. J Am Med Inform Assoc 2008;15:585-600.
[4] Mahoney CD, Berard-Collins CM, Coleman R, Amaral JF, Cotter CM. Effects of an integrated clinical information system on medication safety in a multi-hospital setting. Am J Health Syst Pharm 2007;64:1969-77.
[5] Shamliyan TA, Duval S, Du J, Kane RL. Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors. Health Serv Res 2008;43:32-53.
[6] Shamliyan TA, Duval S, Du J, Kane RL. Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors. Health Serv Res 2008;43:32-53.
[7] Wolfstadt JI, Gurwitz JH, Field TS, Lee M, Kalkar S, Wu W, et al. The effect of computerized physician order entry with clinical decision support on the rates of adverse drug events: a systematic review. J Gen Intern Med 2008;23:451-8.
[8] Campbell EM, Sittig DF, Ash JS, Guappone KP, Dykstra RH. Types of unintended consequences related to computerized provider order entry. J Am Med Inform Assoc 2006;13:547-56.

- *Clear differentiation between similar items:* In order to reduce selection errors, pick lists (eg. for medicines) should be limited in length and should be presented so that it is easy to differentiate between similar items.
- *Reporting capabilities:* Software should have sophisticated reporting capabilities to enable clinicians to monitor clinical care and audit the safety and accuracy of the app itself. Query and reporting functions should be flexible and easy to customise by an average user.

Supporting decision-making on software selection

We welcome the acknowledgement given to the need for consumers and health professionals to be supported in their decision-making around selection and use of devices and apps and the precautions that they need to take in terms of their own IT platforms and networks and we would support any efforts to improve the availability of this type of information and support. Indeed, as a national implementation body, NPS MedicineWise can play a role in helping guide health professionals and consumers on the safe and effective use of software tools that support quality use of medicines and health technologies and we would be happy to discuss ways that we could support future activity in this area.

Look to international approaches

As mentioned, ensuring the safety of software is a very challenging issue and one that many countries including the US, UK and Canada are all trying to tackle. A review of approaches taken by these countries should be a first step. While no-one has really solved all the issues yet, there are valuable insights to be gained from looking at the different approaches being taken and their effectiveness.

Thank you again for the opportunity to provide feedback. We are very happy to provide further clarification or guidance as needed and look forward to our continued collaboration with the TGA in the future.

Yours sincerely,

[redacted]

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