VCGS
Leaders in Genetic Health

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RE: Feedback to Consultation Regarding Scope of Regulated Software Products

Background

The Victorian Clinical Genetics Services (VCGS) is a private, not-for profit genetics service that performs a wide range of genetic and genomic testing. VCGS is one of the largest genetic pathology providers in Australia, and delivers services not only within Victoria but across Australia and internationally. VCGS services encompass the full lifetime of genetic health needs, including pre-conception screening, prenatal, peri-natal and post-natal testing, ranging all the way through to genetic diagnosis for complex genetic disorders later in life.

As an international leader in genetics and genomics, many assays employed by VCGS are highly specialised, and sometimes even novel or unique within the Australian context. Software is a growing component of these assays which are increasingly "data-driven" and based on complex algorithms and large scale data analytics. Due to a rapidly moving technological environment, it is frequently the case that there are not market solutions available and of suitable maturity to support the services VCGS wishes to offer. Therefore, VCGS often builds or heavily customises software to support our unique services.

Responses to Questions

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

  The ARTG serves as a central point of registration for all goods that could result in harm to a consumer when applied for their intended purpose. This role as a central registry has value even if oversight is not directly executed by the TGA but by another body. Therefore, VCGS suggests all software that would ordinarily fall under regulatory oversight of the TGA should be listed in the ARTG, regardless of whether TGA is the body exercising regulatory oversight.

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

  VCGS agrees that the basis for exemptions or exclusions must be that either (a) the risk can be judged a-priori to be negligible or (b) the risk is regulated through an alternative means.

  Pathology in Australia has historically been governed by regulatory oversight from the National Pathology Accreditation Advisory Council (NPAAC), with accreditation of laboratories according to ISO15189:2012 and NPAAC standards administered by NATA and the Royal College of Pathologists Australasia (RCPA).

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Based on the definitions outlined in the consultation document, the analytical software employed by VCGS likely falls under the definition of an in-house software medical device. Without exemption or exclusion, therefore, this software would require regulatory oversight of the TGA. However, this software sits in a very different context to more general software devices that are covered by TGA regulation.

VCGS does not sell or license any of the software components used in delivering its testing services. Rather, these components are used internally within the analytical process for generating test results. Due to this, VCGS has significant control over how the software is used, who is trained to use it, and how risks associated with the software are managed. For example, software results are subjected to both manual and automated quality control checks that sit downstream of the software devices. Additionally, results from the software are never returned "raw" to patients or medical practitioners; they are subject to interpretation by experts who are trained for awareness of quality issues. This holistic approach to quality control is fully examined during NATA / RCPA inspections and risks are identified and mitigated according to NPAAC standards, based on ISO 15189.

Due to this context, regulation by the TGA would be highly duplicative of the existing regulatory regime through NATA and NPAAC. Further, as many of the risks are mitigated through wider laboratory processes externalised to the device, regulatory oversight focused on the laboratory (as conducted by NATA/RCPA) is more appropriate than a device focused approach (as would apply where devices are utilised in a stand alone capacity).

We therefore propose that software within medical laboratories could be excluded from TGA regulation when:

(i) the software sits within an larger quality framework mitigating the risks from its use
(ii) the laboratory is already subject to regulatory oversight that includes the software

It may be that not all aspects relating to safety of software medical devices are fully captured at this time in NPAAC standards. If so, this gap would be ideally addressed through improvement of NPAAC standards themselves or cross reference to existing standards (TGA or otherwise) while maintaining NPAAC and NATA/RCPA as the mechanisms of regulation and oversight.

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

  We do not have a response to this question.