ST VINCENT'S HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

St Vincent's Health Australia Ltd
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Therapeutic Goods Administration
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Standing Committee on Health, Aged Care and Sport
Health.Reps@aph.gov.au

To whom it may concern,

**Consultation: Proposed refinements to the regulation of personalised medical devices**

St Vincent's Health Australia welcomes the opportunity to comment on the proposed plans to deregulate a number of medical devices by exclusion or exemption from the existing regulatory framework.

Because of the interrelated issues being canvassed, we are also taking the opportunity to share this submission with the concurrent "*Inquiry into approval processes for new drugs and novel medical technologies in Australia"* being undertaken by the House of Representatives Standing Committee on Health, Aged Care and Sport.

We commend the TGA and the Australian Government for their ongoing commitment to ensuring that Australia is a global leader in regulating safe and effective Patient-Matched Medical Devices.

About St Vincent's Health Australia

Founded by the Sisters of Charity, St Vincent's has been providing compassionate, high quality health and aged care to the Australian community since 1857. As a Catholic healthcare service we bring God's love to those in need through the healing ministry of Jesus. We are especially committed to people who are poor or vulnerable.

Across St Vincent's, we have 39 facilities comprising:

- 6 public hospitals
- 10 private hospitals
- 20 aged care facilities
- 3 co-located research institutes:
    - Victor Chang Cardiac Research Institute
    - St Vincent's Institute of Medical Research

    - Garvan Institute of Medical Research, and
- 1 co-located partner facility.

Most relevantly to this consultation, in 2016 St Vincent's Health Australia launched the not-for-profit *Advanced Biofabrication Centre* which is the first hospital based multidisciplinary centre in Australia designed to facilitate translational research to improve the health outcomes for Australians. Researchers and clinicians work alongside each other with a vision to replace lost or damaged joints and limbs through tumour, trauma or degeneration.

The Centre is bringing researchers together to drive medical innovations such as re-engineered limbs, muscles, tissues and nerves. It has the capabilities, research and clinical expertise to use new materials and stem cell technologies to drive this vision, and deliver life-changing opportunities for many patients.

The Centre is enabling key researchers and clinicians to explore the real-time development and production of replacement body parts, which can be surgically implanted into patients.

The Centre is a flagship initiative within the eventual Aikenhead Centre for Medical Discovery multi-institutional endeavour. The vision of the ACMD partners is to collaborate in a dedicated hub, fusing medicine, engineering, science and industry to revolutionise how we approach medical solutions to chronic health problems.

St Vincent's has an established track record in health and medical research, as well as clinical trials. Clinicians and researchers based at the Centre will inform basic research with expert clinical insights, identification of unmet patient needs and also translate research findings to patients to drive improvements in clinical outcomes.

<u>Consultation Response</u>

St Vincent's Health Australia remains strongly in favour of maintaining the status quo regulation of all Patient-Matched Medical Devices regardless of their risk classification.

The digitisation of the medical supply chain, coupled with the advances offered by Patient-Matched Medical Devices, has the capacity to deliver not just better clinical outcomes for patients, but more efficient financial outcomes for payers in the health system (taxpayers, governments, insurers, and patients). Australia is currently poised to be a global leader in these significant changes to the medical device supply chain, which for the first time allow for rigorous quantitative safety and efficacy oversight of personalised medical devices.

In our opinion, Australia's current world leading regulatory framework for Patient-Matched Medical Devices:

- Fosters a high level of consumer confidence in device safety and efficacy;

- Provides clinicians with a consistent regulatory environment to ensure that the devices they prescribe are properly regulated within a clearly enunciated liability framework;
- Encourages R&D to develop novel Patient-Matched Medical Devices;
- Facilitates investment into the commercialisation of Patient-Matched Medical Devices; and
- Aligns with the International Medical Device Regulators Forum Definitions for Personalized (Patient-Specific, Customized and Custom-made) Medical Devices.

Subject to the current transition process, the existing regulations require all Patient-Matched Medical Devices to be included on the ARTG. St Vincent's Health Australia submits that this requirement was an important step forward for the regulation of medical devices in Australia and should not be watered down without a very careful consideration of the cost/risk/benefit case for patient outcomes.

Manufacturers of all medical devices (including Patient-Matched Medical Devices) manufactured and/or supplied in Australia should ensure that they have:

- Appropriate conformity assessment procedures in place for the device; and
- Appropriate documentation demonstrating compliance of the device with the Essential Principles.

Depending on the risk class, this may require the device sponsor to make submissions for TGA pre- market review of quality, safety and efficacy data before products are launched in the market. Again, depending on the risk class, there may also be a requirement for medical devices (including Patient-Matched Medical Devices) to have a TGA Conformity Assessment certificate.

Even though this "regulatory burden" may have a potential to slightly drive up operational costs and extending time to market, the consumers' interests in ensuring the safety and efficacy of Patient-Matched Medical Devices are still well- protected today by the substantiated safety and efficacy assurance through the regulatory expertise of the TGA with a regulatory oversight of the scientific evidences together with the relevant conformity assessment procedure.

The consultation paper, on the other hand, has countenanced a number of "exclusions" and "exemptions" from the existing regulatory regime, as well as a number of industry self-regulated processes for conformity assessment.

We respect the likely intent of the consultation paper in attempting to insulate low-volume artisanal fabricators of traditional "custom made" medical devices from regulatory burden. We also respectfully submit that the proposed refinements are insufficiently targeted to actually achieve this objective and do not make the cost/risk/benefit case for the broad-ranging deregulation of medical devices which are proposed.

Conclusion

There is no clear advantage in reforming the existing regulatory framework for Patient-Matched Medical Devices as the consumer benefits are not being manifested.

In view of above, St Vincent's Health Australia strongly recommends that the "proposed refinements" for regulating personalised medical devices including Patient-Matched Medical Devices in Australia not be adopted.

If you would to discuss the contents of this submission, or for more information about our work, please do not hesitate to contact us.

Yours sincerely

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**St. Vincent's Health Australia**