The Royal Australian and New Zealand College of Radiologists®

RANZCR Response to the Consultation on the Therapeutic Products Regulatory Scheme

About The Royal Australian and New Zealand College of Radiologists

The Royal Australian and New Zealand College of Radiologists (RANZCR) is the peak body advancing patient care and quality standards in the *clinical radiology* and *radiation oncology* sectors. It represents over 4,000 medical specialist members in Australia and New Zealand.

RANZCR's role is to drive the appropriate, proper and safe use of medical imaging and radiation oncology services in the community. This includes supporting the training, assessment and accreditation of trainees; the maintenance of quality and standards in both specialties, and workforce mapping to ensure we have the staff to support the sectors in the future.

Clinical radiology relates to the diagnosis or treatment of a patient through the use of medical imaging. Diagnostic imaging uses plain X-ray radiology, computerised tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine imaging techniques to obtain images that are interpreted to aid in the diagnosis of disease. Interventional radiologists treat as well as diagnose disease using imaging equipment.

Radiation oncology is a medical specialty that involves the controlled use of radiation to treat cancer either for cure, or to reduce pain and other symptoms caused by cancer. Radiation therapy is an effective, safe and cost-effective method of treating cancer, and is involved in 40% of cancer cures. Unfortunately, while one in two cancer patients would benefit from radiation therapy, only about one in three will actually receive the treatment. The reasons for this underutilisation are a complex mix of lack of awareness of radiation therapy as a viable treatment option, physical access to a treatment centre, and patients not being provided with comprehensive information about all possible treatment options.

Consultation Feedback

RANZCR welcomes the opportunity to provide feedback on the Therapeutic Products Regulatory Scheme. Overall, the College supports the regulation of therapeutic products. Safe medication, devices and technology is necessary to ensure the best possible care of health consumers in New Zealand.

The College has some concerns relating to the proposed legislation. It is important that the legislation neither stifles innovation, best practice nor creates cumbersome bureaucracy. While we want the products themselves to be regulated effectively, we do not feel it necessary to duplicate regulation on practitioners. The Bill needs to balance the desired intent to ensure medicines, devices and technologies are safe, whilst minimising the increased input costs and bureaucracy which may result.

Restrictions on use

The College does not believe that the usage of products needs as much additional regulation as is currently suggested by the Therapeutic Products Bill. The Health Practitioner's Competence Assurance Act already ensures that health practitioners are competent – it is enforced by the Health and Disability Commissioner, the regulatory authorities for the health practitioners and the Disciplinary Tribunal.

The Therapeutic Products Bill's limitations on product use may restrict a competent professional from providing the best possible care for patients. In particular:

- **Making devices**: Some members of the College work in services that produce some of their own devices. This is both innovative and cost effective, which benefits the patients and the health system overall. The College is concerned that competent practitioners may have their practise unnecessarily restricted by the proposed legislation and its regulatory authority. The College believes the benefits of this type of innovation outweigh the risks as it leads to better equipment and better outcomes. Processes to approve these devices must take this into account – innovation in healthcare should not be reliant on well-funded pharmaceutical companies.
- **3-D printing**: Further to the above bullet point, the College understands that a SCNSA will be required when practitioners use a 3-D printer to create a device. The College would also hope that a stream-lined process is introduced for services that use the technology. It would be unacceptable for treatment to be delayed or unavailable because of the approval process.
- **Off-label prescribing**: The College has concerns about the number of 'special clinical needs supply authority' requests its members will be obliged to submit for off-label prescribing. The College notes that the Ministry intends for the process to be minimal (possibly just a tick box on the prescription). However, the College also believes there needs to be an automated process to approve medications that are most commonly prescribed off-label. Any extra steps in the process must be linked to a legitimate safety concern. The College expects that the most commonly prescribed off-label medications are likely to be safe, even in the absence of a randomised control trial for that particular purpose.

Approvals

- **Approvals**: The College has concerns regarding occasions of overly-limited access and the thresholds for approval - lots of medicine and technology are used and benefit patients but without randomised control trials. Currently, New Zealand relies on well-trained and competent practitioners to make wise clinical decisions regarding use of therapeutic products. While the College understands that in some situations this is insufficient to ensure excellence of patient care, the College would expect that any additional regulations focus on areas of data-driven concern without the need for blanket restrictions on usage of all unapproved therapeutic products.
- **Process and timelines for approval**: While the College expects that the Ministry is also sensitive to the need to have an efficient process for approving products, we suggest that particular attention is paid by the regulatory authority into ensuring it has the right experts to do the assessments and sufficient numbers of those experts to ensure an expedient process. The College also suggests the use of FDA (American) and EU approvals to guide decisions in New Zealand unless there is some discrepancy between other jurisdictions which requires specific consideration for our patients and healthcare system.
- **Research**: The College is concerned that increased regulation will hinder research. Andrew Holden, Director of Interventional Radiology at Auckland Hospital states: "*To date, New Zealand has benefited from a medical device approval system that has allowed physicians and patients in New Zealand to get early access to internationally approved medical devices. This includes devices that have been approved for clinical use by bodies such as the FDA in the US and CE Bodies in Europe. This is in stark contrast to countries like Australia where the TGA provides a much more cumbersome and expensive pathway to product approvals resulting in delays to patient access. In the years I have been involved in Interventional Radiology, I have not seen a patient safety issue as a result of this efficient device approval pathway. This efficient pathway has contributed to our success in the VIRU, employing 3 full time Research Coordinators and contributing to many global advances in vascular treatment. I have concerns that the Therapeutics Products Bill may make access to vascular intervention devices more cumbersome with higher administration costs, resulting in poorer outcomes for patients and reducing the potential for early human research.*"

Amendment to the Health Practitioners Competence Assurance Act - Prescribing and scopes of practice

The MoH consultation document on the Therapeutic Products Bill also includes a recommended amendment to the Health Practitioners Competence Assurance Act that would link prescribing rights to a scope of practice. Changes to prescribing rights will require approval by the MoH as well as the required consultation by the regulatory authority. The College would ask that the consultation processes be robust and include all affected parties, particularly those whose practice may be affected by a new prescriber group.

Radiopharmaceuticals

College members have indicated some support of the regulation of radiopharmaceuticals as there is a view that, currently, the standard of the pharmaceutical compounding may not be of a consistently high standard.

However, members were also concerned:

- that the additional regulations may impede new developments, noting that the FDA has been restricting new developments in the United States of America
- regulating radiopharmaceuticals will see both an increased expense and possibly result in another under-resourced profession: radiopharmacists – there may not be enough of them to manage the increased workload. It would seem appropriate to ensure the nuclear medicine technologists that commonly produce these medicines in New Zealand be able to continue.

Artificial Intelligence – Type 4 products

RANZCR would also like further consideration given by the Ministry to regulation of software as a medical device, and specifically artificial intelligence (AI). It is anticipated that AI products will possibly become Type-4 products but it is worth thinking through the issues prior to introduction of new legislation.

Software used in medicine has advanced significantly in recent decades, a trend we expect to accelerate. There are complex interactions in decision-making between the clinician, the service provider and the software and the health system needs to ensure each component is regulated appropriately in line with their contribution to the service being provided.

Clinical radiology and radiation oncology are two areas of medicine that are data rich and already using advanced technologies and informatics software. Because of this, both are ready to adopt artificial intelligence (AI) and machine learning (ML). RANZCR believes that AI has enormous potential but could also do significant harm if left unregulated or operating autonomously.

RANZCR would like the Ministry to consider the implications of AI and how regulatory mechanisms need to be revised with changes to technology. We would however caution against the creation of a route to market for all AI and machine learning tools in medicine when there is limited understanding of how this space will evolve in the coming years.

RANZCR commenced working on AI in 2016. Our initial focus was to understand the landscape and to inform our membership of advances in artificial intelligence and machine learning and to prepare the ground for the significant changes we foresee. In November 2018, RANZCR organised Australia's first AI in healthcare conference called Intelligence18, which brought together international experts in AI to discuss the latest developments and implications for privacy and the practice of medicine.[1] Also in 2018, the Faculty of Clinical Radiology established an Artificial Intelligence Working Group (AIWG) to consider the implications of artificial intelligence and machine learning on the discipline of clinical radiology and plan a response that includes:

- appropriate education for members, trainees, stakeholders and the public
- how this technology can be applied appropriately and judiciously in the best interests of patients.

RANZCR is proud that we are the first professional body in healthcare to have developed a set of ethical principles for AI. Having reviewed the literature globally and discussed the issues with experts in AI in medicine, the AIWG developed a set of eight ethical principles which are intended to ensure that AI and ML tools, at all times, reflect the needs of patients, their care and their safety, and they should respect the clinical teams that care for them. The ethical principles cover eight areas which include:

- Safety
- Avoidance of Bias
- Transparency and Explainability

[1] https://www.eiseverywhere.com/ehome/index.php?eventid=349139&

- Privacy and Protection of Data
- Decision-Making on Diagnosis and Treatment
- Liability for Decisions Made
- Application of Human Values
- Governance.

RANZCR strongly believes that the regulation of AI needs a strong ethical underpinning and that developers of AI technologies in medicine should demonstrate adherence to an ethical framework.

We have recently published a short paper to inform stakeholders and members about the current status of AI, called the State of Play.[2] The Ministry may find it helpful to use established terms with a common understanding for deliberations.

RANZCR recently responded to a consultation on regulation of SaMD and AI undertaken by the TGA in Australia.[3] RANZCR is also considering what principles should guide the development of a regulatory structure around AI. Furthermore, we are revising our curricula to incorporate learning outcomes for our trainees to equip them to work alongside AI. We will also develop upskilling opportunities for practicing clinical radiologists and radiation oncologists.

RANZCR would appreciate an opportunity to meet with the Ministry to hear your perspective on our work on AI and discuss how we might collaborate on this important matter to ensure it is regulated appropriately.

Implementation of the Therapeutic Products Bill

- **Opportunities for feedback**: It is likely that unforeseen issues will arise post implementation of the new legislation. The College asks that there be an early opportunity to provide feedback so adjustments can be made to the regulatory authority's implementation and policies, and possibly even to the Bill itself.
- **Communication strategy**: This Bill will have far-reaching implications for how healthcare is delivered in New Zealand and needs to be accompanied by an effective communications plan that advises on these changes in a timely manner and reaches all key stakeholders in the health system. This is also important to avoid disruptions to supply of medicines or medical devices which could have severe implications for patients.

The College welcomes the opportunity to further discuss any of the issues raised in this letter. To book a meeting, or if you have any questions, please contact Mark Nevin at mark.nevin@ranzcr.edu.au or +61 2 9268 9755.

Yours sincerely,

Gabriel Lau

Chair NZ Branch - RANZCR

[2] https://www.ranzcr.com/whats-on/news-media/316-ranzcr-artificial-intelligence-in-radiology-and-radiation-oncology-the-state-of-play-2019

[3] https://www.ranzcr.com/whats-on/news-media/319-ranzcr-therapeutic-guidelines-consultation-response-1