

Thursday, 18 April 2019

Ms Sheila Swan Chief Advisor, Regulatory Policy Ministry of Health PO Box 5013 Wellington NZ 6140

Email: therapeuticproducts@moh.govt.nz

Dear Ms Swan,

## **RE: Therapeutic Products Regulatory Scheme consultation**

Thank you for the opportunity to provide feedback on the Government's proposal to establish a new regulatory scheme for therapeutic products through the draft Therapeutic Products Bill. The Australasian Sonographers Association is supportive of these important steps to ensure New Zealanders have access to safe, quality, and effective therapeutic products through effective regulation of the manufacture, importation, promotion, supply, and administration or use of therapeutic products.

As the peak body representing the sonographer profession across Australia and New Zealand, we are particularly interested in changes that may affect sonographers' access to, and use of, ultrasound equipment for diagnostic imaging examinations. Including essential products used with this equipment such as cleaning/sterilisation products and contrast agents.

Having reviewed the draft Bill and consultation documents the ASA is happy to support them in principle, noting there is nothing specific in the information presented that would restrict or impact patients access to sonographer performed medical diagnostic ultrasound examinations.

However, we expect that the detail of the regulation concerning the use of specific categories of ultrasound equipment, and associated products, will be contained within the subordinate instruments to the Bill; being the regulations, rules and notices; which are to be developed. The ASA would be delighted to assist the Ministry to identify an experienced sonographer to contribute to this work.

We highly recommend that the Ministry incorporates the sonographer perspective in the development of regulations and regulator made instruments that govern the use of ultrasound equipment and the essential products used with this equipment, that assure patient safety in providing medical diagnostic ultrasound examinations. This is important to avoid unintended consequences that could impact ongoing patient access to safe and quality medical diagnostic ultrasound services.

If the ASA can assist you in identifying a sonographer participant for this work or have any questions on the above, please contact James Brooks-Dowsett, Policy & Advocacy Adviser, by phone on + 61 3 9552 0008 or email to <a href="mailto:policy@sonographers.org">policy@sonographers.org</a>.



I look forward to working with you to develop and implement this new regulatory scheme in New Zealand.

Yours sincerely,

Jodie Long

Chief Executive Officer

Attachment: Therapeutic Products Consultation: ASA Submitter Profile