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Australian Digital Health Agency



The Australian Digital Health Agency (the Agency) welcomes the opportunity to provide feedback to the Therapeutic Goods Association (the TGA) on the regulation of software, including Software as a Medical Device (SaMD).

Pillar three of the National Digital Health Strategy (2018-22), agreed by all Australian Governments in August 2017, promotes both high-quality data with a commonly understood meaning and a confident health workforce engaging with health technology. The Agency has been tasked with facilitating the delivery of the strategy. An efficient, risk based, safe and effective regulatory system of SaMD would strongly support consumers and their clinicians to use technology confidently to support their care.

The Agency is committed to working closely with the TGA on this important reform.