Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Electromagnetic chairs for urinary incontinence

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Discussion relating to electromagnetic chairs for the treatment of urinary incontinence

Background:

The Women's Health Product Working Group (WHPWG) July 2025 meeting sought information about TGA regulation of electromagnetic chairs used in the treatment of urinary incontinence.

Regulatory history:

Electromagnetic chairs for use in urinary incontinence in the context of pelvic floor muscle strengthening are regulated by the TGA as lower class medical devices (class IIa). They can be found under the GMDN codes *"58762 - Deep-tissue electromagnetic stimulation system, professional"* and *"65016 - Transcutaneous incontinence-control electrical stimulator"*.

These devices are neither invasive nor implantable and have been included in the ARTG since 2018 through reliance on conformity assessments by comparable overseas regulators (COR), predominantly from the European Union. Applications for inclusion of this technology in the ARTG since 2018 have principally claimed substantial equivalence with other marketed devices and relied on indirect clinical evidence. This clinical evidence base has been modest with some studies suggestive of a similar performance to pelvic floor muscle training. It is noted that these devices are considered to carry lower-level risks and there has been no signals suggesting a safety concern for the device type (noting just one adverse event recorded, from 2021, from the product class).

The TGA does not provide a cost-effectiveness assessment as part of the evaluation for inclusion in the ARTG. Criteria are based on the legislated essential principles. Many devices which have COR approval may not be selected for TGA clinical audit. Where a clinical audit has been conducted, these assessments have focused on the sufficiency of the clinical evidence to support the device safety and establish benefits outweigh undesirable effects for its intended purpose.

Ongoing engagement:

The TGA would be keen to understand current concerns raised by the WHPWG and any impacts these devices are having on Women's Health in the community.

Additionally, the TGA notes that any advertising to consumers should be in accordance with the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021, and any reports of non-compliance will be investigated.

Version History

Version	Description of changes	Author	Effective date
V1.0	Original publication	Medical Devices and Product Quality Division	March 2026