Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Medical Devices

Meeting Outcomes – 12 October 2023

- EXTRACT -

The Committee considered six applications and discussion around those applications was consistent with the Requests for Advice.

Energy-based Vaginal Rejuvenation Devices (radio frequency/laser)

Sponsor name	Multiple (13)
Manufacturer name	Multiple (14)
ARTG IDs	Multiple (21)
Devices	General categories of energy-based devices are radiofrequency (RF); carbon dioxide (CO_2); and Erbium:YAG (erbium-doped yttrium aluminium garnet) and Nd:YAG (neodymium-doped yttrium aluminium garnet). Some devices deliver RF in combination with laser.
The Committee advised:	1. Does the Committee consider that there is sufficient evidence for the use of this kind of device in the treatment of conditions such as vaginal laxity, prolapse, menopausal symptoms, stress urinary incontinence or for improvement in sexual function? • **There is insufficient long-term evidence for the use of this kind of device.** 2. Is the Committee aware of this kind of device being used in Australia, and being generally accepted as the gold-standard option, for any specific treatment pathway? • **These devices are certainly being marketed in Australia however they are not generally accepted as the Gold Standard.** 3. Is the Committee aware of any other potentially vulnerable patient cohort that may be impacted if regulatory action were to be taken on this kind of device? • **None other than some breast cancer patients, those with active liver disease, female genital mutilation and thrombophilia.** • **There is an increasing body of evidence as to the safety of vaginal oestrogen for breast cancer patients and decisions regarding their use should be made in consultation with the medical oncologist.** 4. Is the Committee aware of any patient cohorts that may benefit from these devices or treatment options that would be adversely affected if these devices were removed from the market? For example, is this an option for: a. breast cancer patients as a treatment in minimisation of vaginal dryness who may not be able to use hormonal therapies? • **Currently insufficient clinical evidence to support.** b. patients that have undergone genital mutilation, where laser-based devices may be beneficial in the reconstructive procedures? • **Currently insufficient clinical evidence to support use in this patient group.**