



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

PUBLIC NOTIFICATION AND RECOVERY OF THERAPEUTIC GOODS

On 26 November 2010, Dr Larry Kelly, delegate of the Secretary to the Department of Health and Ageing for the purposes of section 41KB of the *Therapeutic Goods Act 1989* ("the Act"), and acting under subsection 41KA(2)(b) of that Act, imposed on **Medical Monitoring Systems Pty Ltd T/A Meditherm**, in respect of the following device set out in clause 1, the requirements set out in clause 2 below.

1. The requirements described under paragraph 2 below are imposed in relation to the following therapeutic device ("the device");
 - **camera thermographic, ARTG number 143474.**
2. The following requirements are imposed on **Medical Monitoring Systems Pty Ltd T/A Meditherm** in relation to the goods described in clause 1.

Medical Monitoring Systems has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as Meditherm) that **Camera, thermographic (MED2000, MED2000 PRO, MED2000 IRIS)** with the **ARTG number 143474** ("the Device") has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically we ask that you note the following:

- (i) the entry for the Device was cancelled from the ARTG on 24 September 2010;
- (ii) Medical Monitoring Systems Pty Ltd requested the Secretary cancel the entry following a request for information and documents from the TGA which included a request for evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 14 requires every medical device to have clinical evidence appropriate for the use and classification of the device; and
- (iii) that there are advertising requirements for therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:
 - a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the ARTG (refer to section 42DL(1)(g) of the Act);
 - that a therapeutic good cannot be advertised in a manner that is likely to be misleading or likely to lead to consumers inappropriately treating potentially serious diseases (see section 4(2) of the Code); and,
 - that goods generally cannot be advertised in a manner that is likely to mislead or deceive (see section 53 of the TP Act).

Please be aware that penalties may apply for breaches of these requirements.

Signed by
Dr Larry Kelly
Delegate of the Secretary to the Department of Health and Ageing
20 December 2010