



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**PUBLIC NOTIFICATION AND RECOVERY OF THERAPEUTIC GOODS**

On 7 December 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 **Health Screening Technologies**, 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");
  - **Electrical impedance scanner ARTG number 152697.**
2. The following requirements are imposed on **Health Screening Technologies** in relation to the goods described in clause 1.

Health Screening Technologies has been instructed by the Therapeutic Goods Administration ("TGA") to notify users that the **electrical impedance scanner** with the **ARTG number 152697** has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically, users of the device were required to be advised that:

- (i) The entry for the Device was cancelled from the ARTG on 4 June 2010;
- (ii) Health Screening Technologies 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 (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 (section 4(2) of the Code); and,
  - that goods generally cannot be advertised in a manner that is likely to mislead or deceive (section 53 of the TP Act).

A handwritten signature in dark ink, appearing to read 'L Kelly'.

Dr Larry Kelly  
Delegate of the Secretary to the Department of Health and Ageing  
21 December 2010