53

[redacted]

08/12/2010 10:59 AM

To [redacted]

cc <Trevor.Byrne@[redacted]

bcc

Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010

[redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

52

[redacted]

08/12/2010 10:58 AM

To [redacted]
cc <Trevor.Byrne@[redacted]
bcc
Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.

[redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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:

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(ii) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

57

[redacted]

08/12/2010 10:49 AM

To [redacted]
cc <Trevor.Byrne@[redacted]
bcc
Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.
[redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

50

[redacted] 08/12/2010 10:50 AM

To [redacted]
cc <Trevor.Byrne@[redacted]
bcc
Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.
Dear [redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

49

[redacted]

08/12/2010 10:55 AM

To [redacted]
cc <Trevor.Byrne@[redacted]
bcc
Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.
Dear [redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

48

[redacted]

08/12/2010 10:54 AM

To [redacted]
cc <Trevor.Byrne@[redacted]
bcc

Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.
Dear [redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

47

[redacted]

08/12/2010 10:54 AM

To "'Julia Miles'" [redacted]
cc <Trevor.Byrne@[redacted]
bcc
Subject FW: MMS letter ARTG requirement

DOCUMENT NOT YET CLASSIFIED

December 7th 2010.
Dear [redacted]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (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) [redacted] 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.

[redacted]

MMS letter ARTG requirment.pdf

DOCUMENT NOT YET CLASSIFIED

45

[redacted]

December 7th 2010.

[redacted] 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, thermagraphic (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) [redacted] 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).

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[redacted]

[redacted]