Recalls & regulations

Since the initiation of the new regulatory system in 2002 by the Therapeutic Goods Administration (TGA), there has been recalls of dental medical devices.

By Roy Hardman

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When the need for a recall has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods, or corrective action, while the Australian Recall Co-ordinator assists by advising the sponsor of the procedures, by notifying agreed third parties and by monitoring the overall action.

Most recalls are not mandated but are sponsor initiated. However, the Procedure is underpinned by the *Therapeutic Goods Act 1989* and the *Trade Practices Act 1974*.

In terms of the *Therapeutic Goods Act 1989*, mandatory recall provisions can be applied when therapeutic goods are cancelled from the Australian Register of Therapeutic Goods; or where therapeutic goods are unlawfully supplied in Australia; or where therapeutic goods fail to comply with a standard. *The Trade Practices Act 1974* contains provisions in relation to the safety-related recall of consumer goods.

The relevant parts of the Act, which are administered by the Product Safety Policy Unit, ***Australian Competition and Consumer Commission (ACCC)*** empower the Commonwealth Minister responsible for Consumer Affairs to take action when notification is not made of safety-related recalls, or where the recall has not been satisfactorily completed .(1)

When the TGA is notified that there has been illegal supply of a regulated device being distributed in Australia by a current sponsor or they have identified a device from whatever class is being imported into Australia they can initiate a direct recall of the device. This is a situation that occurs if a device is being imported via an individual or Dental Professional.

As part of a sponsor's ongoing responsibility and in accordance with section 41FD of the Act, in applying to include a device in the ARTG, the sponsor has certified that:

- the devices comply with the Essential Principles they have available sufficient information to substantiate that compliance with the Essential Principles or have procedures in place, including a written agreement, to ensure that such information can be obtained from the manufacturer within 20 working days
- an appropriate conformity assessment procedure has been applied to the device they have available sufficient information to substantiate the application of those conformity assessment procedures or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working days
- any advertising material relating to the medical device complies with the TGA requirements (2)

Market monitoring by the TGA is a series of activities carried out to ensure the ongoing regulatory compliance and safety of the medical devices supplied to the Australian market.

Monitoring activities may include:

- reviews of technical and clinical information to ensure that compliance with the Essential Principles is demonstrated
- testing to confirm compliance with the Essential Principles
- inspections of manufacturer's or sponsor's records and documentation
- on-site testing of medical devices or taking samples for off-site testing
- audits of distribution records
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts
- trend analysis and reporting to sponsors

The TGA may take corrective action in

accordance with the legislation if problems are found, such as:

- sponsors and/or manufacturers not fulfilling their regulatory responsibilities
- safety concerns about a medical device (2)

Through various Mutual Recognition Agreements for medical device regulation and its participation in the Global Harmonization Task Force (GHTF), the TGA has an obligation to exchange vigilance information with overseas regulatory agencies.

Information will be exchanged on incidents and events where:

- corrective action, including a recall, is to be taken
- there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined.

The TGA will consult the sponsor when preparing a vigilance report to be sent to other regulatory agencies. It is the responsibility of the sponsor to ensure that the manufacturer is aware of the TGA vigilance report, and that any comments that are made by the manufacturer are passed on to the TGA for consideration. The TGA will only consider changes that address inaccuracies in the report. (2)

In some cases as identified recently in Australia, the overseas manufacture has notified the TGA that their device is being supplied without the device being included on the ARTG. In this situation the TGA will investigate and establish the requirement for a recall and what other action is to be taken.

When making the application to include a medical device in the ARTG the person must comply with section 41FD of the Act and certify that:

- the product applied for is a medical device;
- the device is intended for a specific purpose;
- the device is correctly classified;
- the device complies with the essential principles as well as having available and sufficient information to substantiate compliance with the essential principles;
- an appropriate conformity assessment procedure has been applied to the device as well as having available and sufficient information to substantiate the application of the conformity assessment procedures;
- the advertising for the device complies with all requirements;
- the device does not contain any prohibited imports;
- The information included in or with the application is complete and correct.

It should be noted that an offence would be committed if the person made a false or misleading statement in connection with the application or a certificate associated with the application. Severe financial penalties may be incurred.

If the application is successful, conditions will then be imposed on the supply of the medical device. If the conditions are breached various penalties, ranging from suspension or cancellation of the entry in the ARTG to large fines, may be imposed.

Conditions applying automatically to entries in the ARTG under section 41FN of the Act require the person in whose name the entry has been made to:

- Allow an authorised person from the TGA to enter, at any reasonable time, any premises, including premises outside Australia, at which that person, or any other person deals with the medical devices. This is required so that the authorised person can inspect the premises and medical devices and to take samples. It should be noted that the TGA would pay for the samples.
- If requested by the authorised person the sponsor will also need to produce any documents relating to the medical device and to allow the documents to be copied by the authorised person.
- deliver a reasonable number of samples of the medical device within a specified period of time and according to any specified requirements from the TGA;
- have sufficient information to substantiate compliance with the essential principles;
- have sufficient information to substantiate that the conformity assessment procedures have been applied to the medical device;
- have available information relating to changes to the medical device including the product range, the quality management system of the manufacturer of the medical device; give this information to the TGA, if requested;
- under section 41MP, give information to the TGA about any malfunction or deterioration in the characteristics or performance of the medical device or any inadequacy in the design, production, labelling, instructions for use or advertising materials for the medical device, or any use in accordance with, or contrary to, the use intended by the manufacturer that:
- led to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 10 days after becoming aware of the event or occurrence, or led to a serious threat to public health, within 48 hours of becoming aware of the event, or that might lead to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 30 days of becoming aware of the event. (3)

In summary the recall regulations impact directly on the responsibilities of a sponsor and together with post market vigilance give confidence that the device marketed in Australia are supplied in accordance with regulated standards. ◆

References

(1) Uniform Recall Procedures for Therapeutic Goods ISBN No1 920746102 2004

(2) *Australian Regulatory Guidelines for Medical Devices – Version 1.0 April 2010* Page 296 of 330 Part 3 – Post-market Section 22. Post-market vigilance and monitoring requirements

(3) AUSTRALIAN MEDICAL DEVICES GUIDELINES Obligations and Responsibilities of Medical Device Sponsors and Manufacturers Guidance Document Number Version 1.6

Further information on any issue raised in this article can be obtained from:

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:
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All information is quoted from the TGA referenced source. The comments are a guide only and for further clarification of any issue contact with the TGA is advised.