



This is a consolidated version of TGA News, Issue 56, containing full articles as published on the TGA website <<http://www.tga.gov.au>>.

GENERAL NEWS

Fees & payments

2008-09 fees & charges

Changes to the TGA's fees and charges for the 2008-2009 financial year took effect from 1 July 2008. Details are available on the TGA website <<http://www.tga.gov.au/docs/html/feesach.htm>>.

2008-09 annual charges

Annual charges invoices for the 2008/09 financial year will be sent 3 weeks earlier than in the previous year which will allow sponsors more time to review all their ARTG listings. Otherwise, arrangement for processing annual charges largely remains the same as last year and is outlined below:

- Invoices for annual charges will be issued to Sponsors by **11 July 2008** for all products entered on the ARTG as at 1 July 2008. These invoices will form a complete list of product entries for each Sponsor. Any discrepancies or omissions from the list of product entries should be notified to the TGA immediately.
- Sponsors will have more than two months to review the product range listed in the invoice and identify products which should be cancelled (where supply ceased before 1 July 2008) and products for which an LVLV exemption will be sought.
- The due date for payment of the invoice will be **1 October 2008**.
 - The amount due will be:
 - The invoice amount;
 - LESS annual charge (as per invoice) for each cancelled product;
 - LESS the invoice value for each product for which an LVLV exemption has been claimed;
 - PLUS the application fees payable for LVLV exemption declarations (per product).
- Where a reduction to the invoice amount is to be made, Sponsors must forward a copy of the invoice to the TGA by mail or facsimile (02 6232 8222), together with their payment and any cancellation forms and/or LVLV declarations **signed by an authorised officer**.
- Sponsors electing to pay by instalment must ensure the initial instalment is made by the invoice due date. The initial instalment payment must be at least one quarter of the amount remaining after cancellations and LVLV exemptions are deducted. **Note that application fees for LVLV declarations are payable in full by the due date.**

Cancellations

Sponsor cancellations must be made using the cancellation form available on the TGA website <<http://www.tga.gov.au/fees/forms/artg-cancel.htm>>.

Low volume and low value declarations

Applications to declare that the turnover of a product is of low volume and low value in accordance with Regulation 4C of the Therapeutic Goods (Charges) Regulations 1990 should be submitted together with the applicable fee(s) before the due date of payment.

- Applications to declare that the turnover of a product is of low volume and low value must be made on the form available on the TGA website <<http://www.tga.gov.au/fees/forms/lowvolume.htm>>.
- The 2008/09 LVLV applications for products that had no turnover in 2006-07 must be submitted by using 2009-10 estimate of sales. **The TGA may contact you later in the year to validate your estimate.**
- Applications for declarations relating to products invoiced in late 2007-08 must be finalised by the due date specified on the annual charges invoice. The TGA will not accept applications relating to 2007-08 after 31 July 2008.

Electronic invoices

Less than 50% of Sponsors have elected to receive their annual charges invoices electronically. As electronic invoicing improves the timeliness and delivery of invoices, the TGA encourages sponsors to register for receiving their invoices electronically.

- If you would like to receive your invoice electronically, simply complete a registration form available on the TGA website <<http://www.tga.gov.au/fees/forms/elecbilling.htm>>.
- Note that only two (2) email addresses per Sponsor can be accepted.
- Forms should be submitted to the TGA Accounts Receivable Manager by facsimile on 02 6232 8222, or by email to TGA.Accounts@tga.gov.au

Payments

The TGA will again permit Sponsors to spread their liability for annual charges over the financial year in quarterly instalments. The instalment dates for payment of instalments in 2008-09 will be as follows:

Quarter 1	1 October 2008
Quarter 2	1 December 2008
Quarter 3	1 March 2009
Quarter 4	1 June 2009

- Failure to make an instalment payment by 1 October will forfeit the option of making instalment payments for the remainder of the year. The full amount of the invoice will become payable. Failure to pay a subsequent instalment by the due date will also cause the balance of the account to fall due immediately. However transfers of products can not be completed until outstanding amounts are settled in full.
- Sponsors will be able to make payments for annual charges online by credit card (for amounts up to \$15,000) or by direct debit from a savings or cheque account. Details of payment options and a link to our online payment portal are available on the TGA website <www.tga.gov.au/docs/html/feesach.htm#payment>.

Liability for annual charges

Annual charges are imposed under Regulation 3 of the Therapeutic Goods (Charges) Regulations 1990 and represent a cost recovery tax. Annual charges are payable for any entry on the ARTG in respect of a financial year unless the product is declared to have a turnover that is of low volume and low value.

- Annual charges apply in respect of the financial year (or part there-of) and are not adjusted where a product entry or cancellation occurs during the year.
- The TGA has no power for the waiver of annual charges other than for products declared to have a turnover that is of low volume and low value.
- Sponsors that have not advised the TGA of the cancellation of a product by the due date for payment will remain liable for the annual charge for the product(s) as these products will be deemed to have been an entry on the ARTG for 2008-09.
- Sponsors that cancel a product, or have a product suspended or cancelled by the TGA during the course of the year, remain liable for any outstanding instalments that may be due on the product entry.

All enquiries regarding arrangements for 2008-09 annual charges should be directed to the TGA Accounts Receivable Manager on 02 6232 8264 or by email to TGA.Accounts@tga.gov.au.

Low volume & low value exemptions from annual charges

Key points

- A declaration of low volume and low value turnover (LVLV) will be made where the annual charge payable in respect of an entry on the ARTG is, or has been estimated to be, greater than 6.8 per cent of the wholesale turnover of the goods.
- LVLV applications must be submitted for each financial year in which an annual charge is payable together with evidence of the turnover of the goods.
- Applications must be signed by an authorised officer. Penalties apply under the *Crimes Act 1914* and the *Criminal Code Act 1995* for making false or misleading statements and providing false or misleading information or documents.
- A non-refundable application fee must be paid at the time of submission of an LVLV application. A maximum application fee applies where exemption is sought for multiple therapeutic goods.
- The turnover of a therapeutic good or medical device in a financial year is the total value of that good or device as supplied in Australia in that financial year, exclusive of GST.
- Applicants will be notified in writing of a decision to grant an application for a declaration of low volume and low value.
- Sponsors may apply to the Administrative Appeals Tribunal for review of a decision by the Secretary to refuse an application, or an assumed decision to refuse an application.
- The TGA may require additional documentation or inspect records in relation to LVLV applications.

Procedures

To be eligible for an exemption from payment of annual charges a Sponsor must apply for a declaration that the turnover of a registered or listed therapeutic good, or kind of medical device, is low volume and low value, together with evidence of the turnover of that good or device.

Evidence that may be included with an application may include sales records, inventory records, management reports and financial statements. An application fee must accompany the application. A fee is payable for each therapeutic good or kind of medical device for which a declaration of low volume and low value is sought, up to the maximum fee prescribed in the Regulations (see the 'Summary of Fees and Charges' <<http://www.tga.gov.au/docs/html/feesach.htm#fees>>).

To be assessed for an exemption, applications should be submitted prior to, or by, the due date for payment of an invoice for an annual charge.

Applications should be submitted by the due date of the invoice for the relevant annual charges.

Applications seeking a declaration of low volume, low value turnover for a new therapeutic good or kind of medical device approved during a financial year should be submitted by the due date of the invoice imposing annual charges for the financial year.

A low volume and low value declaration will be made where the Secretary is satisfied that the annual charge payable in respect of an entry on the ARTG is:

- greater than 6.8 per cent of the wholesale turnover of the good for the previous financial year or;
- if there was no turnover in the previous year, greater than 6.8 per cent of the value of the estimated wholesale turnover in the subsequent financial year.

Sponsors will be notified, usually within 30 days, whether a declaration has been granted.

Sponsors should note that annual charges are payable if an application has been declined, or if no declaration has been made within 40 days of receipt of the application.

Sponsors may apply to the Administrative Appeals Tribunal for review of a decision by the Secretary to refuse an application, or an assumed decision to refuse an application.

An annual charge may become payable in relation to a therapeutic good or medical device where the actual turnover is higher than previously in an application for a declaration.

- Sponsors must advise the TGA if the actual turnover for an entry on the ARTG for a therapeutic good or medical device is likely to result in the annual charge being less than 6.8 per cent of the turnover value.

The TGA conducts a sample review program to validate applications for therapeutic goods to be declared low volume and low value. This may require Sponsors to supply details of the actual turnover of goods in respect of a financial year. The TGA may also inspect Sponsor's records of sales.

Forms

Application for declaration that turnover is of low volume and low value

<<http://www.tga.gov.au/fees/forms/lowvolume.htm>>

Assistance

TGA Revenue Manager: Facsimile 02 6232 8222 or by email to TGA.Accounts@tga.gov.au.

References

Therapeutic Goods (Charges) Act 1990

- Section 4 establishes annual charges.

Therapeutic Goods (Charges) Regulations 1990

- Sub-Regulation 4B(1) provides that charges are not payable where goods or devices are declared to be of low volume and low value.
- Regulation 4C sets out the matters that may be taken into account in considering an application.
- Regulation 4E sets out the fee for making an application and the maximum fee for multiple applications in a single year.

Regulation 5 makes an annual charge payable where the actual turnover exceeds an estimate included in an application for a declaration in prescribed circumstances.

Low volume and low value turnover thresholds 2008-09

Table 1. Low volume and low turnover thresholds 2008-09

Item	Annual charge	Maximum sales turnover for exemption
Prescription medicine containing a biological active ingredient	\$5,250	\$77,206
Prescription medicine containing non-biological active ingredients	\$3,140	\$46,176
Registered over-the-counter and complementary medicines	\$1,010	\$14,853
Listed therapeutic products and complementary medicines	\$710	\$10,441
Registered medical devices	\$2,170	\$31,912
Registered therapeutic devices (ie IVDs)	\$1,240	\$18,235
Listed medical devices	\$1,090	\$16,029
Listed therapeutic devices (ie IVDs)	\$620	\$9,118
Included medical devices – class I	\$60	N/A*
Included medical devices – class Im and Is	\$500	\$7,353
Included medical devices – class IIa and IIb	\$760	\$11,176
Included medical devices – class III and active implantable medical devices (AIMD)	\$990	\$14,559

*The \$60 annual charge for included medical devices - class I is less than the \$120 low value low volume application fee. It is therefore in the sponsor's best interest to pay the annual charge.

Cost recovery impact statement

Each year the TGA reviews its fees and charges in consultation with industry associations. Generally, fees and charges are increased in line with annual average wage and cost movements. Significant changes to regulatory arrangements of new regulatory proposals involve additional consultation with affected sectors and result in the preparation of cost recovery impact statements.

In developing the 2008-09 TGA operating budget, it was identified that fees and charges in the non-prescription (registered) medicines sector would not achieve full cost recovery. The TGA had proposed significant increases to fees and charges that would move the sector towards full cost recovery [in 2007-08], however a decision was taken to defer action and address the under recovery in the (then) upcoming joint regulatory scheme with New Zealand, the Australia New Zealand Therapeutic Products Agency (ANZTPA).

Given that the establishment of ANZTPA has been postponed for the foreseeable future, and that the non prescription (registered) medicines sector continues to under recover its costs, the TGA consulted with the Australian Self Medication Industry (ASMI) in February 2008 and notified that the ongoing under-recovery would be addressed in 2008-09.

For more information, see the cost recovery impact statement *Annual review of fees and charges 2008-09—Non-prescription (registered) medicines* on the TGA website <<http://www.tga.gov.au/fees/cris-npfees0809.htm>>.

Business plan

The *TGA Business Plan 2008-09* is an integral part of the framework that will guide the TGA's work during the next financial year and identifies continuing responsibilities and major project initiatives planned for this period. The plan is available on the TGA website <<http://www.tga.gov.au/about/tgabp0809.htm>>.

Excluded goods order

Therapeutic Goods (Excluded Goods) Order No. 1 of 2008 was published in the *Commonwealth of Australia Gazette*, No. GN 23, on 11 June 2008.

<<http://www.tga.gov.au/legis/tgeg0801.htm>>

This order replaces and revokes *Therapeutic Goods (Excluded Goods) Order No. 1 of 2005*.

Nanotechnology

The term 'nanotechnology' is used to describe a wide range of methods involved in the production and engineering of structures and systems by controlling size and shape at the nanometre scale.

When used in therapeutics, nanotechnologies have been defined as the application of nanotechnologies (or nanomedicine) for the purpose of making a medical diagnosis or treating disease.

There is now a list of questions and answers about nanotechnology and therapeutic products available on the TGA website <<http://www.tga.gov.au/meds/qanano.htm>>.

BP 2008

From 1 July 2008, the definition of "*British Pharmacopoeia*" in the *Therapeutic Goods Act 1989* is the *British Pharmacopoeia 2008* <<http://www.tga.gov.au/legis/bp2008.htm>>.

NDPSC

Gazette notices associated with the February and June 2008 meetings of the National Drugs and Poisons Schedule Committee and the record of reasons for the February 2008 meeting are available on the TGA website <<http://www.tga.gov.au/ndpsc/ndspcgan.htm>>.

The *Standard for the Uniform Scheduling of Drugs* No. 23 took effect from 1 June 2008. An order form is available on the TGA website <<http://www.tga.gov.au/ndpsc/susdp.htm>>.

NCCTG

The membership details of the National Co-ordinating Committee for Therapeutic Goods have been updated <<http://www.tga.gov.au/docs/html/ncctg.htm>>.

TGC

A meeting summary and a meeting report from the 32nd meeting (April 2008) of the Therapeutic Goods Committee are available on the TGA website <<http://www.tga.gov.au/docs/html/tgcmnu.htm>>.

Recalls

One consumer-level medicine recall has occurred since the last issue of *TGA News*. Full details are on the TGA website <<http://www.tga.gov.au/recalls/index.htm>>.

The recall coordinators list has been updated in the *Uniform Recall Procedures for Therapeutic Goods*. The list is available from the TGA website <<http://www.tga.gov.au/docs/html/urptg.htm>>.

TGA website changes

Since the last issue of *TGA News*, there have been a couple of changes to the TGA website:

- There is now a new topic under the 'Regulation' section: '*IVDs & other therapeutic goods*'. This area contains information about the regulation of in vitro diagnostic devices, sterilants & disinfectants and tampons. <<http://www.tga.gov.au/othertg/index.htm>>
- The chemicals information has been moved off the TGA website and onto the Department of Health and Ageing website <<http://www.health.gov.au>>.

MEDICAL DEVICES

ARGMD

The TGA is developing a consolidated reference document detailing the Australian regulatory requirements for medical devices.

The *Australian Regulatory Guidelines for Medical Devices* (ARGMD) will provide guidance on all the regulatory requirements for medical devices in Australia and will be made available on the TGA website. It will replace the existing guidance documents and information sheets for medical devices.

As each section is prepared, it will be released for comment, with a four week deadline. We welcome comments on the technical aspects of the document. We are keen to have stakeholder involvement in the development of the ARGMD as we want to ensure that the language is easy to understand.

Since the last issue of *TGA News*, a draft *Table of Contents* for the ARGMD has been made available on the TGA website. This shows the structure that is planned for the ARGMD, however please be aware that it will be frequently updated as the need for new information is identified.

The draft section on *Fees & charges* is available for comment with a closing date of 30 July 2008.

<<http://www.tga.gov.au/devices/argmd.htm>>

Standards orders

New MDSOs

Two new medical devices standards orders have been finalised and the updated versions were registered on the Federal Register of Legislative Instruments (FRLI) on 28 May 2008. Both are available on the ComLaw website <<http://www.comlaw.gov.au>> and the TGA website:

- *Medical Device Standards Order (Standards for Clinical Evidence) 2008*
<<http://www.tga.gov.au/legis/mdsoce2008.htm>>

This Order specifies medical device standards relevant to medical devices that require clinical evidence in order to demonstrate compliance with the essential principles.

This Order is for all medical devices for which clinical evidence is required to demonstrate compliance to the essential principles.

- *Medical Device Standards Order (Standards for Risk Management) 2008*
<<http://www.tga.gov.au/legis/mdsorm2008.htm>>

This Order specifies relevant medical device standards for the risk analysis and risk management methods concerning medical devices.

This Order determines medical device standards, which set methods for risk analysis and risk management in order to demonstrate compliance of medical devices with the essential principles.

Draft CASO & MDSOs

The TGA is seeking comments on a proposal to adopt the following four standards orders.

- *Conformity Assessment Standards Order (Standards for Quality Management Systems and Quality Assurance Techniques) 2008*
- *Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2008*
- *Medical Device Standards Order (Standards for Natural Latex Rubber Condoms) 2008*
- *Medical Device Standards Order (Standards for Biological Safety and Biocompatibility of Medical Devices) 2008*

This consultation closes on 15 August 2008. More information and copies of the draft orders are available on the TGA website <<http://www.tga.gov.au/devices/drmdsocas2.htm>>.

Clinical evidence for medical devices

Clinical data may be:

- clinical investigation data
 - data from all formal clinical trials carried out using devices
 - any other experimental use in humans using prototype devices or components for the purpose of developing or investigating their safety and performance
- data from clinical experience, including:
 - manufacturer-generated post market surveillance reports, registries or cohort studies
 - adverse events databases
 - data for the device in question generated from individual patients under Authorised Prescriber and/or Special Access Schemes prior to marketing of the device
 - details of clinically relevant field corrective actions (eg recalls, notifications, hazard alerts)
- data, both favourable and unfavourable, obtained from a review of the literature:
 - specifically about the device in question—where available, this must always be included in any review, and/or
 - for comparative and well-established devices this must include relevant post market information
 - if clinical data is not available adequate justification should be provided to explain how data for a similar device can establish the safety and performance of the device in question.

Clinical data that is not acceptable includes but is not limited to: brochures, testimonials and product description.

Manufacturers must:

- demonstrate compliance with Essential Principle 14 relating to clinical evidence
- compile clinical data
- arrange for a signed and dated clinical evaluation report to be prepared by an expert.

The TGA will:

- ensure compliance with the relevant legislation, including Essential Principle 14
- assess the clinical evaluation report against the clinical data if and when requested from the manufacturer.

The TGA may seek the advice of the Medical Device Evaluation Committee to provide expert advice in relation to the medical device and the documented:

- performance
- safety
- benefit/risk assessment
- compliance with the TGA legislative requirements.

For more information, please see the guidance document *Clinical evidence requirements for inclusion of medical devices in the ARTG* <<http://www.tga.gov.au/docs/html/devguid4.htm>>.

MDEC

A summary of key resolutions and a meeting report from the Medical Device Evaluation Committee's June 2008 meeting are available on the TGA website <<http://www.tga.gov.au/docs/html/mdec/mdecrecords.htm>>.

ADN form

A new form *Australian device name (ADN) nomination form* is now available on the TGA website. This form should be used when proposing a name for a new ingredient used in a formulated medical device. <<http://www.tga.gov.au/devices/forms/formadn.htm>>.

MEDICINES

Adverse drug reactions bulletin

The June 2008 issue of the *Australian Adverse Drug Reactions Bulletin* is available on the TGA website <<http://www.tga.gov.au/adr/aadrb.htm>>.

Articles in the June 2008 issue include:

- Severe skin reactions and venous thromboembolism with strontium ranelate (Protos)
- Statins and muscle disorders—be careful with the dose
- Hepatic toxicity with nitrofurantoin

Medicines committees update

Now available on the TGA website:

- **ADEC:** meeting dates for 2009
<<http://www.tga.gov.au/docs/html/adecc/adecc.htm>>
- **CMEC:** public recommendation summaries for meetings 66 (April 2008) & 67 (June 2008) and extracted ratified minutes for meetings 65 (February 2008) & 66 (April 2008)
<<http://www.tga.gov.au/docs/html/cmec/cmecminu.htm>>

Orphan drugs

Orphan drug products are drugs, vaccines or in vivo diagnostic agents which physicians use to treat, prevent or diagnose rare diseases. The Australian Orphan Drug Program encourages sponsors to market orphan drugs in Australia by reducing costs through waiving fees.

Since the last issue of *TGA News*, six additions have been made to the list of drugs designated as orphan drugs. The complete list is available on the TGA website <<http://www.tga.gov.au/docs/html/orphand2.htm>>.

Medicines labelling

TGO69B

Therapeutic Goods Order No. 69B Amendment to Therapeutic Goods Order No. 69 General requirements for labels for medicines was registered with Federal Register of Legislative Instruments (FRLI) on 6 June 2008.

This amendment updates the definition of 'Required Advisory Statements for Medicine Labels' in TGO69. <<http://www.tga.gov.au/legis/tgo/tgo69b.htm>>

RASML

The *Required Advisory Statements for Medicine Labels* (RASML) was updated in April 2008. The current version and historical versions are available on the TGA website <<http://www.tga.gov.au/meds/rasml.htm>>.

Also available is a consultation document *Required Advisory Statement for Medicine Labels—proposed update 4*, advising stakeholders of proposed changes to the current (April 2008) edition of the *Required Advisory Statements for Medicine Labels*.

Stakeholders are requested to review and comment on the proposed changes.

Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

This consultation closes on 31 July 2008. More information, including how to provide a submission, is available on the TGA website <<http://www.tga.gov.au/meds/drrasml4upd.htm>>.

Listed medicines

Therapeutic Goods (Listing) Notice 2008 (No.3) was registered in the Federal Register of Legislative Instruments (FRLI) on 8 July 2008.

This listing notice relates to preparations containing *Arabinogalactan—Larix*. <<http://www.tga.gov.au/legis/tgnlist0803.htm>>

Product changes in ELF3

The document *Guidance on product changes in ELF3* has been updated <<http://www.tga.gov.au/cm/elf3productchanges.htm>>.

Following the inclusion of a product as a Listed medicine in the ARTG, sponsors may wish to change certain details previously advised to the TGA. Factors such as product stability, manufacturer changes and developing marketing strategies may require changes to product details that were entered at the time of the product's inclusion in the ARTG. This guidance document has been developed to provide assistance to sponsors so that they are able to determine if a change to their ARTG entry for a particular product is necessary and the regulatory impact that making certain changes to currently Listed products may have.

This guidance applies only to medicines Listed in the ARTG for supply in Australia. It does not apply to Registered medicines or medicines Listed in the ARTG for Export Only.

All changes required to be made to existing Listed complementary medicines are to be undertaken via the Electronic Listing Facility Version 3 (ELF 3) system.

Extemporaneous medicines

During April and May 2008, comments were sought on the discussion paper *Regulation of Extemporaneously Prepared Medicines in Non-hospital Pharmacies*. Although the consultation is now closed, the document is still available on the TGA website <<http://www.tga.gov.au/meds/extempcomp2.htm>>.

The discussion paper is the work of the National Co-ordinating Committee on Therapeutic Goods (NCCTG) and is part of the continuing development of an appropriate regulatory response to the changes in the practice of pharmacy that have occurred over recent years. These changes have included increases in the scale of preparation and the variety of ingredients and formulations of extemporaneously compounded medicines.

Alerts & advisory statements

Since the last issue of *TGA News*, the following information has been issued or updated by the TGA. These are all available on the TGA website <<http://www.tga.gov.au/alerts/index.htm>>.

- Human papillomavirus vaccine (Gardasil)
- Recall of blood-thinning medicine—Clexane (enoxaparin)
- The use of cough and cold medicines in children

The following guidelines are available on the Australian Government Department of Health and Ageing website <<http://www.health.gov.au>>.

- *Consensus Guidelines for Australian Clinicians for the use of anti-coagulants during heparin-based product shortages*

INTERNATIONAL ACTIVITY

International visitors & training

In July 2008 the TGA conducted a one-week training program on the evaluation of generic medicines for senior regulatory officials from Thailand, Saudi Arabia, Macau and Korea.

Over recent months, the TGA has also hosted short-term visits with senior officials from Canada, China and Switzerland.

Medical Device Incident Investigations: Recommendations

Don't throw away your samples!!

Too often in our process of investigating adverse events, the samples are not available to assist in our research as to why this event occurred. The need to view the complaint samples whether it is the packaging or the actual medical device can be critical in determining the cause and often the remedy to an adverse event.

The device involved, and its packaging if possible, should be retained so that a more comprehensive investigation of the event can occur.

Please keep your devices until the TGA has received your report and indicated whether we need to inspect the device prior to sending it to the manufacturer.

Some instructions for sending samples are listed below:

1. Clean the device as much as possible without destroying any evidence that you feel contributed to the adverse event.
2. All devices should be double-packaged in plastic bags designed for transporting bio-hazardous objects. The outer package must be clearly labelled with the contents and warnings if the device is contaminated.
3. If the device has sharp edges or components such as suture needles, please pack these items into a sealed plastic container in addition to the plastic bags.

Further information can be found on the TGA website <<http://www.tga.gov.au/problem/iris/devices-testing.htm>>.

Battery in a patient monitor caused a fire

The TGA recently received an Incident Report about a fire occurring in a multi-parameter patient monitor. The fire caused the evacuation of the health facility.

The manufacturer's investigation into the adverse event identified that the root cause of the fire was associated with the battery supplied by a third party. The battery did not have the necessary safety features and continued to receive AC power resulting in continued overheating of the battery.

Batteries supplied by the monitor manufacturer for use in these monitors are specifically-designed batteries to prevent these types of incidents from occurring. Due to safety concerns, the manufacturer of the monitor involved in the incident has advised that the use of batteries supplied by third parties may void the warranty.

This manufacturer has also modified the design of all their new monitors to ensure that third party batteries are no longer able to be inserted into their monitors.

The TGA strongly recommends that the manufacturer's instructions should be followed in relation to the choice and use of batteries in all patient monitors.

Safety Alert: Incorrect loading of the Baxter Flo-Gard IV administration set can cause blood loss

The TGA has received an incident report regarding the incorrect loading of a Baxter Flo-Gard IV administration set which caused blood to be pumped from the patient into the IV solution bag. This event occurred at night but fortunately the patient awoke and discovered the problem.

The TGA tested a pump and infusion set and was able to confirm the reported problem. The sets used in both the incident and the TGA's testing were standard Baxter soft tubing administration sets FNC1165 (see picture) with a slide clamp loading feature. The set is loaded into the infusion pump starting with inserting the slide clamp into the slide clamp slot. The IV line tubing is loaded through the pump mechanism tubing guides (refer to Figure 4 copied from Flo-Gard 6201 operator's manual). However, in the report to the TGA the user had inserted the slide clamp upside down which lead to the patient-end of the tubing being fed through the pump's mechanism guide therefore drawing blood from the patient, through the pump, and subsequently into the medication bag. There is no alarm to indicate that fluid is being drawn from the patient and into the infusion bag.

FNC1165



The TGA has reviewed the Baxter Flo-Gard 6201 Operation Manual and considers it has adequate instructions in regards to loading the administration set. A warning and direction label has been applied to the door of the pump to remind users of the correct way of loading the administration set. Furthermore, information supplied with the pump instructs the user to observe the drip chamber for at least 10 drops after starting the infusion. Trained personnel should be able to load the tubing correctly by following the instructions for use.

The TGA and Baxter Healthcare have not received any other reports of this type in the past two years. However, the ECRI database reported that this problem had been indicated in several Medical Device Reporting (MDR) reports from the FDA since 1992; but, no patient injuries had been reported¹.

These pumps are being used in the home and this report was from a home user. Home users are generally less experienced in the use of infusion pumps. The TGA considers that the instructions for use and warning labels for the Baxter Flo-Gard 6201 may be difficult for users with limited training to interpret and the home environment is also devoid of the safety and support systems found in hospital.

The TGA believes that the consequence of blood loss could threaten patients' lives. The TGA has confirmed with Baxter that this problem can occur with the Baxter Flo-Gard 6301 pump as it uses the same administration set with the same

mechanism for loading administration set as the Flo-Gard 6201.

The result of this investigation has been that Baxter has issued a safety alert to warn home use patients of this problem. Baxter recommend in this safety alert that home use patients use an administration set containing a non-return valve. The use of this type of administration set is that an upstream occlusion will occur preventing backflow of blood from the patient and activating the pump alarm.

Recommended actions

- Please bring this Safety Alert to the attention of all Baxter Flo-Gard 6201 and 6301 users, particularly home users.
- Please refer to the Operator's Manual and labels that are provided with each device for a complete list of all warnings and precautions associated with use of these devices.
- Follow the instructions for use for loading the set into the pump including observing flow from the drip chamber after starting the pump.

The TGA encourages users to report any advert events regarding medical devices to the TGA and the manufacturer to help to prevent further incidents.


Reference

1. "General-purpose infusion pumps" *Health Devices* 1997;26(2) 50-75.

Understanding medical device package labelling symbol

Since the implementation of regulation of single use medical devices in 2003 in Australia, end users of these devices have become more aware of device package labelling and the meaning of those labels. Copies of the *Instructions For Use* are not always available with every device as often there is one copy per box which is discarded when the box is opened. This means that the packaging label is a very important source of information to the user about the product.

The Incident Report Investigation Scheme (IRIS) has received problem reports and calls from healthcare professionals and end users of medical devices seeking clarification on the meaning and interpretation of symbols used on labelling instructions for use for medical devices.

The symbol  is an international standardised symbol listed in ISO15223:2007 "Medical Devices – symbols to be used with medical device labels, labelling and information to be supplied" and means DO NOT REUSE. SINGLE USE is interpreted to mean the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient. Some manufacturers will use this symbol in combination with the words 'SINGLE PATIENT USE'. This is interpreted to mean more than one episode of use of a medical device on the same patient. The device may undergo some form of reprocessing between each use in accordance with the manufacturer's instructions for reuse on the same patient.

The TGA recommends;

1. End users refer to the IFU available with these types of medical devices,
2. Contact the TGA if they have any further enquiries on this subject OR access the TGA website www.tga.gov.au/medicaldevices/sud.
3. Report through the TGA's IRIS any adverse events or problems associated with the labelling and/or use of single use medical devices.

Maintenance of hospital beds—An important issue in preventing injury to patients and staff

Issue: A health worker has sustained a serious injury, amputation of a finger, while operating an electric bed. This incident occurred while two healthcare workers were tending a patient back to bed.

The brake pedal of the bed had loosened and disengaged while the bed was lowered. The weight of the bed was temporarily supported by a retaining washer on the lower edge of the bed elevation mechanism and the out-of-position brake pedal. This was mistakenly believed to be the lowest position of the bed.

The bed was held up for a short time and at the same moment one of the healthcare workers was trying to insert a foot stool under the foot-end of the bed with their hand placed in the gap between the bed and the foot stool.

The bed suddenly dropped from a height of about 3cm and the healthcare worker's ring finger was amputated.

Background: An investigation was conducted by the manufacturer who found:

- The bed's brake was left in a steering position; according to the instruction manual it should always be in the locked position when the bed is positioned or unattended.
- A loosened brake pedal might indicate there is either a lack of 'defective equipment' reporting and response process, or an ineffective routine maintenance program.
- The maintenance schedule does not appear to have occurred as there was no record of this bed being checked in more than twelve months.

Recommendations

- Always consult the manufacturer's instructions prior to operating the bed; this is best covered at orientation for all new employees.
- Ensure problems with bed function are reported and acted on promptly.
- Ensure all beds are inspected annually and an effective maintenance schedule is conducted by an appropriately-qualified technician. Annual inspections should include checking of all fasteners to ensure proper fit, position, and tightness.
- Ensure the brakes are fully engaged prior to raising or lowering the bed.
- Avoid placing foot stools or other obstacles beneath the bed's corner tube as this can create a dangerous pinch point.

Marshall Torrens electrically operated hospital beds— Patient safety issues

Issue: The South Australian Department of Health and the Therapeutic Goods Administration have received reports of incidents where the backrest and wheel mounting supports of Marshall Torrens hospital beds had either broken or had been damaged. Sudden failure of the bed, particularly at the backrest mounting support could result in patient injury.

The South Australian Department of Health has also identified that the bed design presents an unacceptable risk of patient entrapment and is advising hospitals within South Australia accordingly.

Background: Marshall Torrens electrically operated beds were manufactured by Marshall Furniture in South Australia in the late 1990s. This company no longer exists and the TGA has been unable to determine the extent of supply but believes the beds may be isolated to South Australia. It is known that many beds are still in use.

Investigation of these reports have identified that the beds are subject to:

- Metal fatigue at the backrest actuator's mounting point on the backrest, and
- Weld cracks around the wheel mounting supports.

Recommendation

South Australian Department of Health has recommended that in relation to the structural issues:

- Users of Marshall Torrens beds conduct, if not already doing so, a rigorous inspection program of all aspects of bed safety and operation. In view of reports received, particular attention should be given to the structural integrity of the backrest actuator mounting point and the bed caster mountings.
- Where evidence of fatigue is found, the bed should be either taken out of service and replaced, or repairs be carried out to strengthen the area around the backrest mounting or the backrest be replaced with a strengthened design.
- Although it may be possible to strengthen the area around the backrest mounting, the thickness of the material is such that it may allow transfer of stress and, as a result, metal fatigue may recur at a point beyond the repaired area. Therefore, regular ongoing inspection of the beds is recommended, regardless of whether they have been previously repaired.
- Hospitals that decide to repair or replace the backrest frame support or to replace the backrest frame with a strengthened design need to be aware that any such modification will infer manufacturer status on the hospital along with the associated product liabilities.

For detailed advice please contact South Australian Department of Health:

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- If you are not in South Australia and have some of these beds please report this to the TGA and follow the instructions above.

Misconnection of electrosurgical bipolar electrodes

The problem of misconnection of Electrosurgical Bipolar Electrodes in the surgical environment continues to be challenging.

The TGA has recently received a report of an experienced operating theatre staff member misconnecting bipolar electrodes into an electrosurgical unit (ESU) monopolar terminals. A literature review has revealed that serious adverse events associated with electrosurgical misconnection have also occurred abroad. The misconnection occurs when the two connectors of the bipolar electrode are accidentally plugged into two of the three monopolar terminals. It appears that this potential for misconnection exists with all brands of electrosurgical bipolar electrodes that have banana-type plugs mounted on flexible cables (see Figure 1).

When misconnected, the bipolar electrode may cause the ESU to inadvertently activate without operator initiation or control. If the monopolar power output has been programmed into the ESU (eg been left at its previous setting), the patient or operator can suffer serious burns or electric shock.

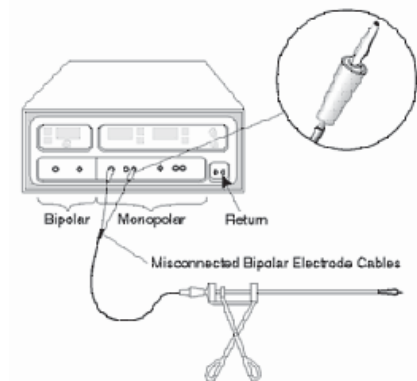


Figure 1. Flexible bipolar electrode cables can allow misconnection of bipolar leads into the monopolar jacks, resulting in serious patient injury.

The activation mechanism for the hazardous monopolar current was described by Reeter in 1990: "The closed forceps short-circuit the ESU's switching circuit and turn on the monopolar current."

ECRI also published an article on bipolar electrode misconnection in 1993:

If the bipolar electrode leads are plugged into the active monopolar jack and either one of the monopolar switching jacks, the ESU will be inadvertently activated when the tips of the bipolar forceps either 1) touch and short the leads together or 2) span the tissue with low enough impedance to permit activation.

Once activated the bipolar electrode will continue to hazardously discharge electricity until the electrode is unplugged or the ESU is turned off. Serious harm may occur during the time taken to deactivate the electrode.

The International Electrotechnical Commission (IEC) parent standard medical electrical device safety requires all patient circuit connections to be so designed that they cannot be hazardously connected to wrong outlets. Similarly, the Australian national parent standard for medical electrical device safety requires the design and construction of bipolar electrodes to prohibit misconnection:

56.3 Connections – General

a) Construction of connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented were a SAFETY HAZARD may be caused.

Recent amendments have been implemented in the IEC 60601-2-2 Part 2-2: Particular requirements for the safety of high frequency surgical equipment, which states:

*46.104

a) ACTIVE OUTPUT TERMINALS on HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT shall differ in configuration sufficiently such that MONOPOLAR ACTIVE ACCESSORIES, NEUTRAL ELECTRODES and BIPOLAR ACTIVE ACCESSORIES cannot be improperly connected. See Annex AA

b) ACTIVE CONNECTORS having more than one pin shall have fixed pin spacing. "Flying leads" are prohibited.

c) ACTIVE CONNECTORS having no more than a single pin need not be investigated.

It is hoped in the future that manufacturers will now take on this information and this problem should be lessened.

In the meantime the following recommendations are made for operating theatres.

Recommendations

1. Alert staff to the hazards of misconnecting the electrosurgical bipolar electrode to the ESU monopolar terminals. The greatest risk is presented to the patient and operator who may be exposed to uncontrolled electrosurgical current at monopolar power levels.
2. Ensure that the bipolar electrode is connected to the proper ESU terminals before operation.
3. Consider using bipolar electrodes that are designed to prevent misconnection.
4. Implement procedures that require the monopolar electrode to be plugged in before the return electrode (eg thigh pad) is plugged into the ESU.
5. Implement procedures that require all ESU output/operating modes to be set to their minimum until the surgeon is ready to proceed in that mode. An output mode should remain at its minimum setting throughout an operating procedure until that mode is required. If an output mode is no longer required during a procedure it should be set to its minimum output.

References

1. A.K. Retter, "Bipolar Forceps Misconnection Hazardous" *OR Manager* Feb 1990; 6(2):13.
2. Anonymous, "Misconnection of Bipolar Electrosurgical Electrodes" *Health Devices* Jan 1995; 24(1):34-5.
3. IEC 60601.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*. The 'particular' standard does not specifically refer to bipolar electrodes requiring design and construction that prevents misconnection: IEC 60601.2.2: 1999 *Medical electrical equipment – Part 2: Particular requirements for the safety of high-frequency surgical equipment*.
4. AS 3200.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*, Clause 56.3 a), p. 89. AS 3200 series is based on the IEC 60601 series.
5. IEC 60601-2-2 Fourth edition 2006-07 *Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment*, pgs 59 .

Medical Device Incident Report Investigation Scheme (IRIS) Statistics Report 01/04/2008 to 30/06/2008

Number of device incident reports received: 279

The full IRIS statistics report for the period 01/04/2008 to 30/06/2008 is available on the TGA website <<http://www.tga.gov.au/problem/iris/statistics.htm>>.