

CONFORMITY ASSESSMENT BRANCH (CAB)

Providing a means of communication on issues affecting the quality, safety and efficacy of materials, equipment, instruments, apparatus, implants and appliances used in health care.

Please circulate to all interested staff

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- 2.
- 3.
- 4.



Commonwealth Department of
Health and
Aged Care

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MEDICAL DEVICES ELECTRONIC APPLICATION LODGE MENT (DEAL) – VOLUNTEERS REQUIRED FOR PILOT LODGE MENT SYSTEM

An integral element of the new harmonised regulatory arrangements for medical devices in Australia will be an electronic lodgement system. The TGA, in consultation with industry, is developing an electronic lodgement process for medical device applications. The electronic process is now available for testing as a pilot program.

The devices system will provide an electronic online environment for the lodgement or variation of a Medical Device entries on the Australian Register of Therapeutic Goods (ARTG). This will enable sponsors of therapeutic goods to lodge applications from a remote Internet-capable PC electronically to the TGA through a secure transmission system. In support of these applications, access will be provided to persons external to the TGA to legally access appropriate electronic Medical Device information entered on the ARTG.

The electronic facility will assist the TGA and industry to cope with the procedural changes that will arise from the new harmonised regulatory system. The purpose of the Pilot system is to provide an efficient and effective means for sponsors of medical devices (or their agents) to electronically submit device applications to TGA and to provide a facility to assist TGA to assure the ongoing safety and quality of devices in Australia.

The DEAL lodgement process will move TGA processes and procedures for medical devices towards self-assessment by the applicant seeking entry of the device on the ARTG. Medical devices

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will be processed subject to the class of device and risk under the new harmonised scheme.

Under the new system medical devices considered to be:

- low risk (Class I) will be automatically entered on the ARTG under DEAL but may randomly be subject to a pre-entry review;
- low risk (Class I measuring or sterile devices) will be entered on the ARTG following verification of the manufacturers certification. These devices will be subject to random pre-entry review;
- medium risk (Class IIa and IIb) will also be entered on the ARTG following verification of the manufacturing certification. These medical devices will be subject to random pre-entry review; and
- high risk (all Class III and Active Implantable Medical Devices (AIMD)) will be reviewed prior to entry on the ARTG.

Medical devices dealt with under the new harmonised scheme will not be 'listed' or 'registered' as the terms are currently understood. They will be entered on the ARTG by their 'Class'. This new terminology is required to distinguish the classification of devices under the harmonised system, as it incorporates types of products which are presently registered, listed or exempt from the requirements of the *Therapeutic Goods Act 1989*.

The proposed system is not simply an electronic form. The DEAL software enables the TGA to determine the correctness of the application and instructs the applicant on required product information. In addition, the software has the ability to inform sponsors of their self assessment and co-regulatory obligations. The applicant is required to make a declaration that the product is eligible for inclusion on the ARTG and the information contained within the application is truthful and accurate. The applicant is also required to validate the safety of the product and conformity with relevant standards.

Documentation supporting the application will not be required to be submitted at the time of the application.

The entry of a device on the ARTG can have two distinct stages subject to the classified risk of the device. For example, a Class I application can be made directly against a manufacturer's self declaration of conformity.

The applicants role in the DEAL process is as follows:

- For medium to high risk devices, an initial application of a manufacturer's conformity assessment will be required. Unlike current work practices where a conformity certificate is required per application, the assessment will be for the full product range defined by the conformity certificate; and

- The device application can be made and product details entered. Where relevant, information such as ECRI/UMDNS code, approval route and Class will be cross linked to the conformity assessment verification.

Once an application is received by the TGA, those products not required to undergo a review will be automatically recorded on the ARTG. Applicants will be notified of the allocated ARTG number.

For those 20% of products requiring a full review, the system will generate an applicant notification requesting relevant documentation for assessment. Upon completion of the review, the applicant is notified of the outcome and, where approved, notification that the reviewed device has been recorded on the ARTG and informed of the ARTG number.

It is proposed that the pilot development provides:

- a Medical Devices application lodgement system;
- a Manufacturer Conformity Assessment application lodgement system;
- a mechanism for an applicant to manage applications (create, view, recall, edit, archive, print, validate and lodge applications into TGA);
- a job tracking facility (provides the ability for TGA to receive and monitor the progress of applications); and
- a client access capability (provides the ability for a client to view appropriate subsets of the TGA database to check on ARTG application status or to submit requests to update that data).

The pilot development will include extensive consultation and final review by relevant industry and health professional stakeholders. Co-operation and support from industry is essential for a successful implementation of the lodgement facility, which is envisaged for late September 2000.

Volunteers to be pilot sites are urgently required. For further information on becoming a volunteer or if you have any questions concerning the device application lodgement process please contact Mike Johnston on phone (02) 6232 8403, facsimile (02) 6232 8687 or E-mail: michael.johnston@health.gov.au.



UPDATE ON THE PROPOSED NEW MEDICAL DEVICE REGULATORY SYSTEM

The drafting of legislation to implement the new regulatory system for medical devices has been delayed due to higher government priorities. The TGA will issue an exposure draft of the Bill to stakeholders and it is now likely that the new legislation will come into force late 2000 or early 2001.

The Medical Devices Harmonisation Working Party (MDHWP) met on 8 December 1999 and on 30 March 2000. Issues discussed at the December meeting included post-market regulatory requirements, the information data set for the Australian Register of Therapeutic Goods and education and training strategies. Issues discussed at the March meeting included review of Export Certification, update on the Medical Devices Electronic Application Lodgement (DEAL) and regulatory requirements for Class I devices under the new regulatory framework for medical devices.

Fact sheets on the proposed new medical device regulatory framework are available on the medical devices web page at: <http://www.health.gov.au/tga/docs/html/medinfo.htm>.

Further information on the new medical device regulatory framework can be found at: <http://www.health.gov.au/tga/devices/devices.htm> or contact Shane Clarke on phone (02) 6232 8576, facsimile (02) 6232 8687 or E-mail: shane.clarke@health.gov.au.

STAKEHOLDER CONSULTATION ON NEW DEVICE REGULATORY PROPOSALS

The TGA will commence stakeholder consultation shortly on a number of medical device regulatory issues including:

- Review of Therapeutic Goods Order (TGO 64) for tampons;
- Labelling of Medical devices (including a review of TGO 37);
- Proposed regulation of Class I devices.

Whilst a comprehensive mail out to stakeholders will be undertaken, comments on such proposals are invited from all sectors of the community. Full details of current consultative issues may be found in the medical devices pages of the TGA website at: <http://www.health.gov.au/tga/devices.devices.htm> (consultation documents - current).

NEW PROPOSED FEES AND CHARGES FOR MEDICAL DEVICES

The TGA moved to 100% cost recovery in 1998/99. At that time, a 33% efficiency gain by the TGA was returned to industry in the form of a discount on the income that would otherwise have applied following the move from the original target of 50% cost recovery.

Following extensive negotiations with the peak medical devices industry organisation, the Medical Industry Association of Australia (MIAA), agreement has been reached for a new schedule of fees and charges for medical devices for 2000–2001. The projected total revenue of \$7 million has been achieved by doubling the 50% cost recovery base from 1996/97.

There is no general across the board percentage increase in the fees and charges, and in some instances there is a reduction. For example, the listing application fee will be reduced from \$300 to \$240 whilst the annual charge for listings will increase from \$300 to \$450. The fees and charges schedule has been finalised after several months of discussion with the MIAA.

There is greater emphasis on annual charges as a revenue base with a rationalisation of other fees giving a more equitable balance across the evaluation fees schedule.

The new charges will come into effect as of 1 July 2000 and the new fees will take effect on the date of gazettal. This is anticipated to be mid May. Copies of the new schedule of fees and charges may be obtained from the TGA Publications Office on 1800 020 653 or from the TGA website <http://www.health.gov.au/tga/devices.htm> when they come into effect.

PURCHASING MEDICAL DEVICES VIA THE INTERNET

As the use of the Internet becomes more widespread, Australians are increasingly using the Internet to buy medical devices.

The Australian regulatory system is designed to ensure that Australian consumers can be confident that medical devices approved for marketing in Australia meet acceptable standards for quality and safety. This assumption cannot be made for medical devices imported from overseas via the Internet. Products purchased on-line from overseas may not have been subject to adequate quality control.

In general, individuals are permitted to import small quantities of most medical devices for their own personal use provided that certain conditions are met. The prior approval of the Therapeutic Goods Administration (TGA) is not required if:

- the goods do not contain a substance which is prohibited, controlled or subject to other specific embargoes. Prohibited imports include drugs such as psychotropic substances, antibiotics, narcotics, anabolic and androgenic substances and abortifacients;

- the goods are for use by the importer or a member of the importer's immediate family and are not sold or supplied to any other person.

Overseas-based suppliers are subject to their own country's regulatory requirements. Medical devices ordered over the Internet are subject to Australian Customs. Furthermore, online suppliers based in Australia are subject to Australian legislation.

Medical devices must be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. The TGA encourages users to only purchase and use medical devices that are included on the ARTG. Consumers need to be aware that medical devices ordered directly from overseas may not have been evaluated by TGA for quality, safety or performance.

While it may be more convenient to buy medical devices online, it is important consumers seek advice from health professionals regarding appropriate safe use of any medical device.



REVIEW OF THE ADVERTISING ARRANGEMENTS

In April 1999 a review of the advertising arrangements was initiated. The Therapeutic Goods Advertising Code Council (TGACC) was given the task of undertaking the review and consulting with interested groups.

In November of last year, the TGACC forwarded a number of recommendations to the Parliamentary Secretary to the Minister for Health and Aged Care, Senator Grant Tambling. One of the recommendations that Senator Tambling accepted was a new Therapeutic Goods Advertising Code. Under the new Code, sponsors must hold an appropriate level of evidence to support the claims made.

Consultation was held with medical devices associations on 22 February 2000 to update stakeholders on the review of advertising controls and to discuss issues relating to advertising approval and complaints handling.

Currently, Medical Devices are not required to undergo preclearance of advertisements intended for radio/television broadcast or publication in the mainstream print media. Similarly, the complaint handling system (implemented via the Complaints Resolution Panel (CRP)) does not have jurisdiction to consider medical device complaints.

The meeting, with medical device associations, agreed to progress the amendments to the Therapeutic Goods Regulations to ensure complaints against medical devices that are advertised direct to the public in the mainstream media are subject to consideration by the CRP.

The Meeting did not agree to devices being subject to mandatory preclearance at this stage.

There are a number of regulatory changes that are necessary prior to the new advertising arrangements being implemented, and it is anticipated that these will be in place by early April 2000.

In recognition of the need to facilitate a smooth transition and in order to provide as much information to sponsors as possible, a sub-committee of the TGACC has been established to develop an education and communication plan for the introduction of the new advertising arrangements. The sub-committee has developed 'fact sheets' and a TGACC webpage outlining the new arrangements has been developed as part of the TGA website at <http://www.health.gov.au/tga/tgacc.htm>.

The sub-committee travelled to the major capital cities and held public information sessions from 10–19 April. Further details on the new arrangements can be obtained from the TGACC Secretariat on phone (02) 9460 2796 or facsimile (02) 9460 2798.



WRAP-UP FOR Y2K AND MEDICAL DEVICES

Y2K has come and gone. The transition was uneventful in Australia, with no centres reporting any device-related difficulties. By 3.20am AEST (12.20am AWST in Perth) on the morning of 1 January, a central reporting website, set up by the Biomedical Engineering Department of Royal Adelaide Hospital was able to report the all clear from the major hospitals and Health Departments in all states and territories of Australia.

This was particularly significant because, other than New Zealand, Australia was among the first to experience the transition 'live', and much of the rest of the world was looking to Australia/New Zealand for an early warning of things to come.

A similar result was seen worldwide. In the period after the rollover, the Emergency Care Research Institute (ECRI) published a summary of reports received worldwide on their website – some minor events were noted, but these generally involved date reporting and display or printing difficulties with records, etc. **In no instance was patient safety compromised.**

The only device failure to receive significant attention worldwide was with GAMBRO AK100 and AK200 dialysis units. The devices exhibited a problem with the automatic disinfection cycle of the machine, and only if the machine was working through automatic disinfection during the midnight rollover – normal operation of the dialysis cycle was not affected in any way. Further analysis by the manufacturer indicated the problem existed at **every end**

of year transition and not just 1999/2000. A Safety Alert was issued by the device sponsor in Australia and the manufacturer has advised that the fault will be corrected in the next software release.

As with many institutions, preparation for the Y2K rollover involved a significant amount of work and correspondence with device sponsors for the TGA. Letters were sent to **1109** medical device sponsors in September 1998 advising them of the need to conduct formal year 2000 compliance analysis for all medical devices supplied to the Australian market, including superseded devices. These were followed up by further correspondence in April/May and October 1999 to those who had not replied, or had supplied insufficient information in their original response.

During the process, **35** sponsors indicated they were undertaking upgrade or notification programs to users, which would not be complete by 31 March 1999 — the original deadline for completion indicated in the September 1998 letter.

Follow up with these sponsors indicated all upgrade programs were complete before the end of 1999. In some instances the upgrades were described as 'forklift upgrades' and were undertaken late in December or early in January, involving complete replacement of systems with new equipment — this was particularly so with some radiology systems, where room downtime was not possible until the holiday break.

One sponsor had their products removed from the Australian Register of Therapeutic Goods because they failed to satisfy the TGA there is no risk of death, serious illness or serious injury as a result of the operation of the devices at the time of the 31 December 1999/1 January 2000 date rollover. This action was taken on 18 October 1999. The products were reverse osmosis water purification systems for use with haemodialysis systems.

Four sponsors undertook formal safety alert notification, hazard alert notification or recall action under the Uniform Recall Procedure for Therapeutic Goods to correct devices currently in use.

Apart from the need to ensure the ongoing safety of medical devices in use, the TGA program had a secondary benefit, both for sponsors and the TGA. Close scrutiny of device and sponsor details held in the Australian Register of Therapeutic Goods, as a part of the required compliance analysis, resulted in many sponsors taking the opportunity to 'tidy up' their listings and registrations.

A similarly uneventful transition was noted at the second significant date transition for the year — 28–29 February. Although some devices were reported as non-compliant for this date, the non-compliances related to rolling from 28 February to 1 March, and skipping 29 February completely. These date-related issues were easily rectified, and in no instance was patient safety compromised.



LATEX SENSITIVITY

Latex sensitivity is a reaction to natural rubber (latex). Substances (allergens) contained in latex rubber products cause these allergic reactions. These substances may be natural proteins in the raw latex, or chemical additives used in rubber manufacturing.

Latex reactions are occasionally severe enough to be life threatening. The number of latex allergic reactions is increasing and this is probably due to an increasing use of latex products. Around the home dish washing gloves, baby bottle teats and toys may contain latex. A great many medical devices including condoms, incontinence aids, syringes, tourniquets, enema equipment, vial stoppers and stethoscopes also contain latex.

There are three main types of reaction to latex products. These are:

- **Irritation** - when latex is encountered a rash may occur which is dry and itchy. This irritation is often not an allergy, but a reaction to chemicals, soaps or disinfectants used with the latex. The irritation and the resulting skin damage may make it more likely that a true latex allergy will develop later.
- **Delayed Reactions** - are often caused by an allergy to the chemical additives used in latex manufacture. Also known as *allergic contact dermatitis*, these reactions can appear up to 48 hours after exposure and often appear as a red rash on the back of the hands and between the fingers, the skin may blister and become leathery. The severity of this reaction varies.
- **Immediate Reaction** - this reaction is usually a response to the natural protein found in latex. Symptoms, such as local or generalised itchy patches and swelling, generally appear within about 30 minutes of exposure. If mucous membranes are affected, rhinitis conjunctivitis or respiratory difficulties may result. In extreme cases a very sudden and severe response known as anaphylaxis can occur, which causes respiratory difficulties and a drop in blood pressure. Fortunately, these severe reactions are very rare.

People who use latex frequently are at greater risk, although anyone can develop latex allergy. Risk groups include:

- health care professionals and other people who work with latex;
- people who are regularly exposed to latex as a result of medical problems; and
- people with a personal or family history of allergies, especially those with sensitivity to certain foods, and people with a family history of asthma, eczema, or hayfever.

Health professionals and employers should be aware of the potential for latex sensitivity and, if possible, provide alternatives to latex products.

The New South Wales Health Department Human Resources Policy and Strategy Unit in conjunction with the NSW Department's Centre for Clinical Policy and Practice has established a Working Party in relation to latex sensitivity.

The Working Party plans to develop a policy and guidelines for public healthcare facilities, which promote the following outcomes without compromising infection control principles:

- minimalisation of the incidence of sensitisation to latex products among patients and healthcare workers;
- protection of the health and safety of latex allergic patients and health care workers; and
- provision of appropriate information for manufacturers, suppliers, purchases and users.

As part of the process, the Latex Allergy Working Party developed a discussion paper that was distributed to area and rural health services and other interested groups, including industry, seeking comments.

Any questions in relation to this matter should be directed to Ms Frances Walters, Executive Officer, Latex Allergy Working Party, NSW Health Department on phone (02) 9391 9850.

If you work with latex, incidents of latex sensitivity should be reported to the Occupational Health and Safety area of your workplace.

Incidents involving allergic reactions to medical devices should also be reported to TGA's **Medical Device Incident Report Investigation Scheme on 1800 809 361 (free call)**.



NEW EDITION OF THE UNIFORM RECALL PROCEDURE FOR THERAPEUTIC GOODS NOW AVAILABLE

Even with the best manufacturing procedures, mistakes and other unpredictable events can result in defective or unsafe products being released for distribution, with the potential for such goods to cause harm to the people who use them. Labelling errors, product mix-ups, microbiological problems, loss of sterility, contaminants, physical defects in devices, electrical faults and software problems are some of the reasons for recalling medicines and medical devices from the market-place.

The *Uniform Recall Procedure for Therapeutic Goods* (URPTG) sets out the actions to be taken by sponsors and health

authorities when therapeutic goods are to be removed from supply or subjected to corrective action for reasons relating to their quality, safety or efficacy. The URPTG is the result of an agreement between the therapeutic goods industry, the Commonwealth and State/Territory health authorities, consumers and the Consumer Affairs Division of the Department of Treasury (formerly the Federal Bureau for Consumer Affairs). Essentially, the URPTG requires that recall activity be co-ordinated via the Australian Recalls Co-ordinators in the Secretariat & Recalls Section of the Conformity Assessment Branch, Therapeutic Goods Administration; that the recall strategy and recall letters/advertisements be approved, and that follow-up reports on the outcome of the recall and the remedial action taken to prevent a recurrence of the problem, be provided to the co-ordinators.

The December 1996 edition of the URPTG was recently reviewed by the TGA in consultation with the organisations mentioned above. The revised URPTG refers to 'medical device' in place of 'therapeutic device' and 'medicine' instead of 'drug'. Other amendments concern the inclusion of a description of a new recall provision under section 30B of the *Therapeutic Goods Act 1989* (which provides for individual batches of a product to be recalled), and name changes of government departments and Ministers. There are also numerous changes in respect of names and contact details of Commonwealth and State/Territory Recall Co-ordinators and Poison Centres Co-ordinators. The National Co-ordinating Committee on Therapeutic Goods has endorsed the revised URPTG and recommended that it be published as a January 2000 edition.

There were 216 recalls of therapeutic goods in Australia in 1997, 218 in 1998 and 229 in 1999. Approximately two-thirds of the products recalled are medical devices and one third are medicines. Most device recalls require that products be recovered from hospitals whilst most medicine recalls require that affected products be recovered from pharmacies and other retailers. In instances where it is necessary to try and stop all usage of a product, a consumer level recall is conducted. There were 42 consumer level recalls in 1997, 14 in 1998 and 6 in 1999.

Copies of the January 2000 edition of the URPTG will be distributed to all sponsors and hard copies will also be available from the TGA Publications Office. The URPTG will be available on the TGA website in the near future at <http://www.health.gov.au/tga/>.



MEDICAL DEVICE REGISTRATION STATISTICS

The TGA Device Registration and Assessment Section has been working steadily to reduce processing times and backlogs in applications to register medical devices for the



THERAPEUTIC DEVICE EVALUATION COMMITTEE (TDEC) – 1999/4 AND 2000/1 MEETING REPORTS

Australian market. The Section has for some time been working to a target of 90 working days for finalisation of applications, and this has recently been refined by process mapping of the work practices, to set time lines for each stage of the process.

Results for the 99/00 financial year to date have been pleasing. The number of submissions received has increased significantly over the 98/99 financial year, from an average of 30 per quarter to 44 and 36 (representing 52 devices) for the first two quarters of the current year. At the same time, the number processed has increased from an average of 36 per quarter to 42 and 44 for each respective quarter this year. The average processing times for the current year, which remain of most interest to sponsors, have decreased to 77 days for the July to September quarter, and to a record time of 38 days for the October–December quarter. The backlog of applications in progress is decreasing steadily.

It is the aim of the Section to give sponsors a decision of acceptance/rejection of the application for evaluation within 10 working days of receipt, and to this end, pre-evaluation meetings are held at least once per week. The aim of pre-evaluation is to examine the data presented for each submission, to decide on suitability and completeness, and to decide on the scope of evaluation required for the device, so that evaluation fees can be set.

To assist the evaluation process of applications in the most efficient manner, it is important for sponsors to present data in the correct format. For example –

- All data must be in English;
- Sponsors should provide a table of contents indexed to all pages in the accompanying data submission;
- The submission should be filed in a hard cover loose-leaf binder complete with cover page, tabs for major sections, and unique volume and copy identified;
- Where data is contained in more than one volume then the indexing system used should indicate the particular volume number and then the total number of volumes submitted eg Volume 2 of 3;
- Sponsors should take care to submit data in folders that do not fall apart, or that folders are not over-filled – being unable to access pages easily is frustrating and time-consuming for the evaluator;
- Sponsors are also asked to submit four copies of data; this allows simultaneous evaluation of component data, and therefore substantially reduces processing times; and
- Where multiple copies are submitted, then each copy should be appropriately labelled as Copy 1, Copy 2, etc.

Substantial deficiencies in the completeness or rigour of material provided for evaluation may result in the application being rejected at the pre-evaluation stage. New fees will be payable if a rejected application is resubmitted.

The 99/4 and 2000/1 Meetings of the Therapeutic Device Evaluation Committee (TDEC) were held at the TGA Symonston complex on Friday 10 December 1999 and Friday 31 March 2000.

The major issues discussed at the 99/4 meeting were:

- The program for managing Year 2000 (Y2K) compliance of medical devices;
- TDEC's endorsement of the evaluations of three registrable medical device applications and subsequent approval for entry of the products on the Australian Register of Therapeutic Goods (ARTG);
- TDEC's consideration of a fourth evaluation and recommendation the application for registration be approved once the sponsor satisfied a number of conditions;
- Complications associated with the use of Lap Band gastric banding devices implanted for the treatment of obesity;
- Possible injury associated with the use of lung function test equipment on patients receiving *Bleomycin*; and
- Consideration of the outcomes from meetings of TDEC's Advisory Panels on Cardiovascular Devices, Reproductive Devices and Ophthalmic Products.

The major issues discussed during the 2000/1 meeting were:

- A review of the abridged evaluation processes;
- A review of the Global Harmonisation Taskforce (GHTF) Summary Technical File pilot;
- Consideration of new technology associated with a specific brand of pacemaker;
- The regulatory requirements for disinfectants, including consideration of approvals and rejections of disinfectant evaluations;
- A problem report investigation which lead to significant changes to the design of a pacemaker lead;
- A second problem report regarding blood leakage from a pump used for extracorporeal membrane oxygenation and cardiopulmonary bypass procedures; and
- The establishment of the Australian Council for Safety and Quality in Healthcare.

The 2000/2 TDEC Meeting will be held at the TGA Building, Symonston, ACT on Friday 21 July 2000.



INCIDENT REPORTS

Incident reports are published in this bulletin to assist health care professionals and sponsors of products work with the TGA to promote the safety, quality and efficacy of medical devices. They are based on information supplied to the TGA that may not be independently verified as to its accuracy, completeness or causal relationship to the product or its supplier.

A sample of incidents reported over the last three months, along with outcomes from our investigation process is provided below.



St Jude Medical Silzone – Coated Master Series Mechanical Prosthetic Heart Valves and Silzone-coated Annuloplasty Rings.

Silzone coating is a thin application of elemental silver onto the sewing cuff of some of the models of St Jude Medical mechanical heart valves and annuloplasty rings. The Silzone coating was designed to reduce the incidence of endocarditis, a serious complication associated with prosthetic heart valve implantation.

On 26 November 1999, the registration of all Silzone coated heart valves and annuloplasty rings was cancelled from the Australian Register of Therapeutic Goods (ARTG) and an immediate urgent recall was initiated. Similar action was taken concurrently in New Zealand.

This action was initiated by the TGA on the advice of the Cardiovascular Devices Advisory panel of the Therapeutic Devices Evaluation Committee (TDEC). The Panel considered information received from the United Kingdom Medical Devices Agency (MDA), the valve manufacturer and from a Canadian Cardiac Unit and found an increased incidence of thromboembolic events in patients implanted with the Silzone treated valve.

The reasons for the Cardiovascular Devices Advisory Panel advice were:

- the serious safety concerns raised by the MDA, which were supported by data from the Toronto group;
- the absence of demonstrated benefit in the prevention of endocarditis claimed for the Silzone coating; and
- the availability in Australia of equivalent valves from the same manufacturer without Silzone coating.

The Cardiovascular Devices Panel made the additional recommendations that:

- the TGA action should not include any recommendation to explant Silzone valves;
- should any valves be explanted for other clinical reasons, they should be returned to TGA for expert analysis; and
- TGA should communicate with relevant clinicians to establish the actual history of adverse events related to Silzone valves and to ensure that clinicians are sufficiently informed to adequately manage their patients.

On 21 January 2000, St Jude Medical initiated an urgent worldwide recall of Silzone coated prosthetic heart valves

and annuloplasty rings. The St Jude recall action was in response to a recommendation on 21 January 2000, by the AVERT study's Data and Safety Monitoring Board, which after review of the statistical analysis and individual case reports, recommended that patient enrolment in the trial should be discontinued. The recommendation was based on indications that in the AVERT study there is a higher explant rate due to paravalvular leak (leakage around the outside edges of the valve) for mechanical valves with Silzone coating compared with conventional St Jude mechanical heart valves.

This world-wide recall action did not include any recommendation for explant of the already implanted heart valves.

It is not known whether the higher incidence of paravalvular leakage which led to the world wide recall, and the higher incidence of thromboembolism reported earlier are related. However, both were associated with Silzone coatings.

A Hazard Alert was sent to all known Australian users of this type of valve to alert them of this latest development. The TGA is preparing a formal follow up with clinicians to ensure that they are fully informed and are in the best position to care for Australian patients with Silzone implants. This action will include the circulation of advice and a questionnaire to all implanting physicians and cardiologists responsible for management of valve recipients. This process is being conducted with the assistance of the TDEC Cardiovascular Devices Panel.

It should be noted that neither the current world-wide recall nor the earlier Australian recall apply to other uncoated St Jude Medical heart valves which have a long history of safe, effective service.

Recommendations

It is recommended that Silzone coated heart valves not be explanted unless a clinical evaluation of the patient's symptoms indicate explantation. Normal follow-up and monitoring of patients should be undertaken to detect any evidence of paravalvular leakage and to assess compliance with anticoagulant therapy. Patients should be encouraged to report any new symptoms for assessment.

All instances of complications resulting in explantation and/or other injury should be reported to both St Jude Medical Australia on (02) 9565 5399 and the TGA's Incident Report Investigation Scheme on 1800 809 361.



THERAPEUTIC GOODS ADMINISTRATION INCIDENT REPORTING AND INVESTIGATION SCHEME STATISTICS REPORT

Device Incident Reports 01/10/1999 to 31/12/1999

Number received 104

Type Of Problem

Biocompatibility	2
Contamination	7
Diagnoatic Inaccuracy	4
Electrical	11
Fails TGO/Standard	1
Labelling/product Info	7
Material/Formulation Deficiency	20
Mechanical	36
Other	22
Packaging	6
Potency	1
Product Mix Up	2

Cause of Problem:

Biocompatibility	1
Component failure	19
Contamination	3
Design	4
Diagnostic Inaccuracy	1
Electrical	6
Inadequate Instructions	2
Labelling	3
Maintenance	2
Manufacture	9
Material/Formulation Deficiency	15
Mechanical	4
Not Device Related	11
Other	17
Packaging/Sterility	4
Quality Assurance	8
Unknown	19
Wear/Deterioration	3

Potential Effect

Death	4
No Injury	71
Serious Injury	15
Temporary Injury	14

Actual Effect

Death	8
No Injury	76
Temporary Injury	20

Injured Party

Not Applicable	16
Operator	1
Patient	87

Source Category

<i>Administrator</i>	
Medical	2
<i>Clinician</i>	
General Practice	1
Specialist	6
<i>Government Agencies</i>	
Bureau Consumer Affairs	1
Coroner	9
Recall Co-ordinator	3
TGA CAB	1
<i>Nurse</i>	
Community	2
Hospital	8
<i>Other</i>	
Blood Bank	10
Competitor	1
Hospital Supply Service	28
Other	1
Patient/User	3
Sponsor	15
<i>Overseas Advice</i>	
ECRI	3
EU Vigilance	2
FDA	1
Other	2
<i>Para Medical</i>	
Physiotherapist	2
<i>Technical</i>	
Blomed Engineer	3
Result of Investigation	
Bulletin Article	1
Company Warned	1
No Further Action	44
Not Investigated	28
Other	8
Problem Not Confirmed	6
Product Improvement	13
Recall/Hazard Alert	3
Refer to GMP	7
Safety Alert	6
User Education	2

Oxylog 2000 Transport Ventilator

TGA recently received an Incident Report involving a Drager Oxylog 2000 ventilator.

A doctor set the controls for Tidal Volume and Rate on the ventilator to produce an appropriate Minute Volume ventilation rate. After a few minutes, the doctor was alerted to a low oxygen saturation of the patient when an external pulse oximeter monitor sounded an alarm. He then noticed that the end buttons on the control knobs had rotated clockwise approximately 45 degrees from their correct position so that the actual settings were lower than indicated by the markings on the buttons.

As a result of this report, TGA inspected a sample of the Drager Oxylog model 2000 in the SouthCare Rescue helicopter at Canberra Airport. The end buttons of the two largest knobs (Tidal Volume and Rate) had white, engraved lines which normally align with the white lines on the sides of the knobs.

It was possible to remove the buttons from the knobs, using only a fingernail, and re-install them at a different angle so that the line on the button did not indicate the actual control setting. The lateral pointer (a white line on the side of the knob) did indicate the actual setting, but from certain points-of-view this was not visible, for example, when the ventilator was bridge-mounted above a stretcher in a helicopter. As this is a ventilator that is commonly used in an emergency situation, incorrect setting may result in a serious injury or death of a patient.

In the Canberra sample, the buttons could not be easily rotated while attached to the knobs, but it is possible that other ventilators may have buttons that are easier to rotate. There is no positive indexing mechanism to prevent buttons rotating independently of the knobs.

Recommendation

Rotary control knobs on the Oxylog 2000 should be fitted with indexed or keyed end buttons. In the meantime, users should take care when setting critical parameters. PLEASE NOTE: Even though the Tidal Volume and Rate knobs were the only ones affected in the original incident, the design of other rotary knobs is similar. This recommendation consequently applies to all rotary controls on the Oxylog 2000.

Drager Australia have begun a voluntary Recall for Product Correction during which they will replace control knobs with an improved design incorporating indexed end buttons. For further information about the Recall contact Jim Collins of Drager Australia on 03 9265 5000 or TGA's Incident Report Investigation Scheme on 1800 809 361.

DIR 11745 R299/221

Elastomer Driven Drug Infusors

Incident

The incident reported to the TGA involved the connection of elastomer driven drug infusors to the intra-venous line without removing the end cap.

The device supplied by Baxter Healthcare, was originally made with a white end cap, which was difficult to remove. Following complaints from users the cap was changed. The new cap was red and while it was much easier to remove, the new cap had a luer connection on the end and could therefore be connected to the IV line. The end of this cap was blind with the result being that the fluid and medication was not being infused when the device was connected in this way.

Following reports to the sponsor about this new problem, the company has again made changes to the end cap. This time the cap is blue in colour, can be removed easily and it has a blind end that cannot be connected to an IV line.

When the problem of the red end cap was discovered the sponsor sent a notification letter to users to inform them of this problem while a new cap was sourced. There appears to have been some communication problems, as some carers are still connecting the device with the red cap still in place.

In addition, there were still some devices being used with the red caps as well as the blue caps. The TGA did not consider that the sponsor needed to recall the devices with red caps as they had already sent out notifications about the problem and the sales representatives were also talking about this problem to their customers.

Recommendation

There may still be a small number of devices with the red cap in circulation while the switch over to blue caps is taking place. Please be aware that the caps, irrespective of colour, should be removed prior to connection.

DIR 11728

Concern Over the Use of Lung Function Testing Machines Utilising 100% Oxygen on Patients Receiving Bleomycin Therapy.

Incident

The Incident Report Investigation Scheme received a report from a respiratory scientist concerned about patients having treatment with the antineoplastic antibiotic Bleomycin and being tested for lung volume using cardiopulmonary diagnostic systems. The reporter noted that the diagnostic method being used frequently to measure lung volume is nitrogen wash out. The test requires inhaling 100% oxygen for 3–7 minutes. The use of high levels of oxygen on patients taking Bleomycin is contraindicated.

Bleomycin therapy and interaction with administered oxygen

Bleomycin is a powerful antineoplastic agent used in the treatment of a variety of cancers, including germ cell tumours of the testes, Hodgkin's and non Hodgkin's lymphoma, and squamous cell carcinomas of the head, neck, cervix and oesophagus. Although effective in the treatment of these malignancies, Bleomycin is associated with pulmonary morbidity in as many as 10% of patients receiving systemic therapy and increases in frequency when associated with advanced age (older than 65) and dose greater than 300 Units. The Martindale Pharmacopaea states at least 10% of Bleomycin recipients will develop lung damage due to the toxic effects of the treatment, and there is an overall mortality rate of at least 1%.

There is still some dispute over the mechanism of pulmonary injury in humans but the histopathological changes include hyperplasia, destruction of type I and II pneumocytes, and alveolar wall and capillary damage. Donat and Levy (Donat and Levy *J. Urology*: 160, 134-52, 1998) argue that 'Bleomycin exerts a toxic effect via the production of free radicals, which supports the association of exposure to supplemental oxygen with pulmonary toxicity in patients who receive Bleomycin.' Therefore it has been accepted practice for anaesthetists to only give room air percentage oxygen to patients receiving Bleomycin.

Lung function testing

Patients having treatment with Bleomycin may have reduced lung function. Their lung volume will be monitored and it is likely that they may be monitored using devices such as the **Sensormedics Lung Function Diagnostic Unit**, the **MedGraphics Elite Series Plethysmograph** and **Profiler Pulmonary Function System** which are based on a nitrogen wash out test. The Nitrogen wash out test requires the patient to breathe 100% oxygen for 3–7 minutes until there is as little nitrogen remaining as possible.

To test for diminishing lung capacity these tests are conducted serially. Therefore it is possible that cumulative lung damage may occur to patients receiving Bleomycin therapy from repeated exposure to 100% oxygen during lung function testing.

Please note that there is no question of the quality and safety of any of these devices or indeed that of devices of this type, other than when they are used to measure the lung function of patients being treated with Bleomycin.

The four companies who supply the cardiopulmonary diagnostic systems have, on a recommendation from the TGA, agreed to issue a product notification to users of lung function testers alerting them of this concern. The companies are now in the final stage of issuing this notification to all their customers. The product notifications will briefly outline the problem stated above and state alternative methods of measuring lung volume in these patients.

Bristol-Myers Squibb Pharmaceuticals was contacted and they have now amended their product literature to include the new warnings about the increased risk of pulmonary toxicity when oxygen is given in any clinical situation.

Recommendations

Users of lung function testing systems based on flushing of nitrogen with 100% oxygen should check that the patient is not on Bleomycin therapy. The recommended test to use on these patients is one that uses oxygen at normal air levels (21%).



The Use of Nebulisers on Patients Who Have an Endotracheal Tube Inserted

The TGA was notified of an incident involving the attachment of a nebuliser directly onto the end of an endotracheal tube.

This occurred on a patient who was breathing through the endotracheal tube attached to a T-piece. The T-piece was disconnected and a nebuliser containing salbutamol was connected straight onto the endotracheal tube. Oxygen was run at 61L/min. The patient arrested after 30 seconds, however, was successfully resuscitated.

The connection of the nebuliser and anaesthetic equipment is 15mm in diameter, which is the Australian and International standard for anaesthetic breathing circuits and accessories. Normally there are other connectors used to connect the nebuliser to the T-piece, in this incident this connection was an oversight. This incident highlights the need of all staff to be vigilant and the importance of following recommended procedures.



LETTER TO THE EDITOR: DIABETIC TEST STRIPS

The TGA received a letter to the editor of the Australian Therapeutic Device Bulletin. The letter refers to Issue 40–2/99, December 1999 and the article being replied to is under the heading of 'Incident Reports', Diabetic Test Strips.

The letter is reproduced below:

'Dear Sir,

The recommended action is absolutely right and is very essential. But from my experience, the information is not sufficient, and I would like to suggest that besides the 'use by date' one should check the colour shown on the bottle (containing the strips).

Normally there is a 'unopened expiry date' mentioned on the bottle and the packet. One is supposed to use all the strips before this date. Besides using the strips before this expiry date,

one has to use the strips within four months after first opening the bottle. Now this four-month period can be much earlier than the 'use by date' or 'unopened expiry' date.

Secondly, the handling of the bottle and closing the cap of the bottle are equally important. If the strips are exposed to open air for a long time, the strips become ineffective and are likely to give erroneous reading. It is therefore necessary that in case of doubt, and taking into consideration the above possibilities, one should compare the colour of the strip and compare it with the ideal colour given on the bottle. If the colour of the strip has darkened, it is likely to give erroneous reading.

Thus one has to check 1) use by date, 2) use the strips within four months after opening the bottle and 3) if the colour of the strip is darkened or is different than the one shown on the bottle, don't use the strip.

These are my suggestions.

Wishvas Rane'

(Pune, India)

Recommendations

Space is usually provided on test strip containers for users to write down the date the container was opened. Strips are usually fit for use 3–4 months after the container is opened. Users should write down the date of opening and ensure that the strips are either used up 3–4 months from that date, or discarded.

A colour change in an unused the test strip, regardless of age, will obviously indicate that there is something wrong and that the strip, and any others remaining in the container, should not be used. However, expired strips may not always change in colour.

Thank you to Mr Rane for highlighting this need for additional information.

DIR 11519



MEDICAL DEVICE LISTING NEWS

Endoscopic accessories

The TGA thanks sponsors for responding to our request for information regarding endoscopic accessories.

After consultation with the Medical Devices Industry Association (MIAA) in Canberra and a subsequent review of product information, the TGA proposes to amend the definition of an endoscopic accessory to read:

- 'Endoscopic accessories are devices used specifically with endoscopes and no other medical devices to perform endoscopic procedures'

Under the new definition, endoscopic accessories will include surgical instruments such as endoscopic scissors, needle holders, probes, clip appliers, staple guns and suturing devices.

However, endoscopic accessories do not include powered devices, electrosurgical instruments, irrigation/aspiration devices and equipment, catheters, trocars, cannulae, implantable devices, sutures, ligating clips, video processor, camera or drapes.

The TGA will amend the relevant listings for products currently marketed. To facilitate the process, the TGA has designed Notification forms for sponsors to complete the details of products currently covered by the single line ARTG entry for sterile endoscopic accessories.

All sponsors of these products will receive a package in the mail, containing further information and notification forms. Annual charges will be payable for any new listings created.

Processing Times

The Device Listing Section is striving to ensure that the processing time for applications does not exceed 30 days.

However, there has been recent delays due to the quality of applications and GMP evidence submitted.

To assist with the processing of applications, sponsors are asked to ensure that the:

- completed application is an original (please do not send photocopies);
- signature of the authorised person is an original;
- application is dated;
- relevant pages are completed, including manufacturer's site address/s;
- relevant documentation, including labels and GMP preclearance notifications accompany the application.

GMP Preclearance

Sponsors are urged to submit GMP evidence for preclearance prior to submitting listing applications.

To reduce the incidence of rejection due to unsatisfactory GMP evidence, it is important that when submitting GMP evidence the sponsor ensures that the:

- certificates are in English or accompanied by an English translation;
- attachments to the certificates are included;
- certificate is current;
- scope of the certificate covers the device to be listed;
- manufacturer name and address on the certificate is consistent with the name and address on the application and product labels.

The Device Listing Section will issue a single Section 31 letter regarding unsatisfactory GMP evidence. If the

subsequent GMP evidence submitted is then deemed to be unacceptable, the application will be refused. The 11th Edition of Standard of Overseas Manufactures lists the type of GMP evidence that may be submitted in support of a device listing application.

For further information on the above please contact the Medical Device Listing Unit on (02) 6232 8048, facsimile (02) 6232 8785 or E-mail: CAB Medical Device Information@health.gov.au.

APEC SEMINAR AND ASIAN HARMONISATION WORKING PARTY MEETING

Siepie Larkin, Acting Head of the Policy & International Liaison Section, Conformity Assessment Branch, recently attended a two day Asia-Pacific Economic Cooperation (APEC) Seminar on Harmonisation of Medical Equipment Regulation followed by a one day meeting of the Asian Harmonisation Working Party (AHWP) in Singapore.

The APEC seminar and the AHWP were well attended with over forty representatives from Government and Industry from the following countries: Australia, Brunei, Chinese Taipei, Hong Kong, Japan, Korea, Malaysia, New Zealand, Philippines, Singapore, Taiwan, Thailand and the USA.

APEC

The APEC seminar was open to both government regulators and medical device industry representatives from Asia Pacific countries. The objective of the seminar was to increase the awareness of APEC's involvement in medical equipment trade and the benefits of regulatory harmonisation in the region, and to increase familiarity with the harmonised standards and procedures that have been produced by the Global Harmonisation Task Force (GHTF).

The seminar provided participants with an overview of GHTF goals and a history of GHTF activities and achievements. Members from each of the four GHTF study groups gave an overview of progress in the following areas: Pre-market Requirements, Vigilance and Post-Market Surveillance, Quality System Requirements and Manufacturer Auditing. Participants were advised that the GHTF has formally endorsed 14 guidance documents which can be implemented by national governments.

Australia, as one of the five founding members of the GHTF has been instrumental in the move to global harmonisation of the regulation of medical devices. Indeed Australia is currently developing a scheme for the regulation of medical devices which is based on the European Community system and the principles of the GHTF. Drafting instructions for the

required legislative changes have been issued and pending Parliamentary approval it is expected that the new system will be implemented in 2001.

Asian Harmonisation Working Party

The AHWP meeting, chaired by Dr Clarence Tan from the Singapore Ministry of Health, concentrated on formalising the membership of the working party and also finalising the Terms of Reference.

The aim of the AHWP is to recommend ways to harmonise medical device regulation in the Asian region with global trends and to work in coordination with the GHTF and APEC. The AHWP also hopes to work towards recognition of a common audit and a harmonised system of medical device vigilance reporting for adoption within the Asian region.

Membership of the Working Party is going to consist of one Industry and one Regulatory Authority representative from each participating Asian country with a provision for additional observers who can attend but have no formal voting rights. The following six countries have agreed to formal representation on the Working Party Chinese Taipei, Korea, Malaysia, Philippines, Singapore, Thailand, with Hong Kong electing to retain observer status for the moment.

Current AHWP members hope to expand membership at the next meeting, now that the Terms of Reference have been finalised. The next meeting will be held in conjunction with the next GHTF meeting, in Canada in September 2000.

Australia, which is not represented on the AHWP because it is a GHTF founding member, will continue to be invited to attend meetings as observers and as expert consultants on GHTF issues and directions.

REPORT ON THE FEBRUARY 2000 GHTF AD HOC PROCEDURES GROUP MEETING

On 23–24 February 2000 the second meeting of the Global Harmonisation Task Force (GHTF) Ad Hoc Procedures Group was held in Santa Clara, California. The group comprises of regulatory and industry representatives from the European Union (EU), Canada, the United States of America (USA), Australia and Japan as well as observers from England, the USA, France, Germany and Finland. Australia was represented by Rita Maclachlan, Acting Director of the Conformity Assessment Branch and Barry Evers-Buckland of the Medical Industry Association of Australia (MIAA).

GHTF Ad Hoc Procedures Group



During the meeting, work progressed on three draft documents related to GHTF guiding principles, the organisational structure, and definition of roles and responsibilities for those involved in GHTF activities. Consensus was reached on the documents entitled 'Guiding Principles', 'Roles and Responsibilities' and 'Operating Procedures' respectively. Development of these documents is an important milestone in the evolution of the GHTF since they define the framework within which it will operate. Following wider consultation, the Ad Hoc Procedures Group intends to present these documents for discussion and endorsement at the Plenary Session of the upcoming GHTF Conference.

In addition, the Ad Hoc Procedures Group renewed its commitment to act as an advisory body to the Chair. In this capacity, three Study Group documents were endorsed as final documents (Labelling requirements for Medical Devices, Role of Standards in the Assessment of Medical Devices and the Essential Principles of Safety & Performance of Medical Devices) and two Study Group documents were deemed suitable for external consultations. Other agenda items included discussion on work plans submitted by Study Group Chairs, the ongoing work on the revision of ISO 9000 and ISO 9001 and plans for the next GHTF Conference.

The next GHTF Conference will be held in Ottawa from 17–22 September 2000. To date, the Conference program includes Study Group meetings, open Study Group sessions, regional meetings and special topic sessions on issues such as re-use of medical devices and medical device nomenclature.

Since 1998, the Chair of the GHTF has been held by the North American region divided between the USA and now Canada for a three year period. The Chair of the GHTF will rotate next to the Asia Pacific region for a three year period. Australia will assume the Chair in early 2001 for the first 18 months to be followed by Japan for the second 18 month period.

Information on the GHTF can be found on the GHTF website <http://www.ghtf.org/>. Final draft study group documents are posted for 3 months for comment before they are adopted as GHTF 'final draft' documents.



21ST MEETING OF THE NOTIFIED BODIES FOR MEDICAL DEVICES (NB-MED)

Keith Smith represented the TGA at the 21st Meeting of the Notified Bodies for Medical Devices on 2–3 November 1999 in Brussels. The TGA participates in its capacity as a Conformity Assessment Body (CAB) under the Australia-EC Mutual Recognition Agreement (MRA).

The NB-MED Group prepare consensus statements and recommendations in relation to matters of interpretation of the Medical Devices Directive (93/42/EEC), Active Implantable Medical Device Directive (90/385/EEC) and the In-vitro Diagnostic Directive (98/79/EEC). Many of these recommendations are forwarded to the European Commission's Device Expert Group and may become the basis for a MEDDEV guidance document. MEDDEV and NB-MED documents are the generally agreed interpretation of the Directives in relation to medical devices.

The meeting considered several recommendations relating to:

- the treatment of computers used to program implantable pulse generators;
- reporting of design changes and changes to quality systems combination of CE Marked and non-CE Marked medical devices and non-medical devices; and
- the draft recommendation for technical documentation.

There were also several new issues raised for discussion at the meeting including the clarification of software, washing machines for instruments, Class I devices placed on the market in sterile condition, or with a measuring function, and custom made products (such as otoplastics to take hearing aids).

Classification and definition of some medical devices generate significant discussion and it was evident that the European requirements could be interpreted in many different ways. For example:

- Is a washing machine for dental hand pieces a medical device, an accessory to a medical device or an accessory to an accessory of a medical device?

- Are biological indicators a medical device?

The best approach to minimise interpretation is to allow the manufacturer to establish the intended purpose and to strictly apply the definitions in the Directive. If it is unclear, ask the manufacturer to clarify in writing his intention in a particular situation. In most cases this will resolve classification issues. The manufacturer must, however, take care that they can demonstrate that the product will perform as intended and that all foreseeable risks with the use of the product have been considered.

The European Commission and other external working groups/committees presented several reports including:

- the status of Mutual Recognition Agreements between Europe and other trading partners;
- MEDDEV 2.5/5 Medical Devices incorporating materials of animal origin;
- Classification of invasive electrodes;
- Re-use of single use devices;
- Drug/Device issues;
- Global Harmonisation Task Force Documents;

Copies of NB-MED and MEDDEV documents can be found at www.mueller-lierheim.com (follow the links to Regulations, Guidance Documents).

The Notified Bodies meeting was advised that the Australian Government had announced some weeks prior, that new legislation would be introduced for the regulation of medical devices, modelled on the European system. It was also reported that Australia was keen to continue with confidence building activities provided for in the Australia-EC MRA.

Further details may be obtained from Keith Smith on phone (02) 6232 8704, facsimile (02) 6232 8785 or E-mail: Keith.M.Smith@health.gov.au.

INFORMATION FOR SPONSORS OF MEDICATED OR FORMULATED DEVICES AND DISINFECTANTS

Sponsors of disinfectants which are included in the Australian Register of Therapeutic Goods (ARTG) as medical devices are required to submit ingredients in Australian Approved Names (AAN) format. Applications for medicated devices (eg steroid eluting implantable pacing system leads, bone cement containing antibiotic) or formulated devices (eg contact lens cleaning solutions) are also required to submit medicinal substances in AAN terminology.

The 1999 edition of the TGA approved terminology for medicines CD ROM is now available. The CD ROM assists the sponsor in completing application forms for entry of medicated or formulated devices onto the ARTG and assists TGA officers in the processing of applications received as both parties are using the same Australian approved terminology.

Copies of the AAN CD ROM are available from the TGA Publications Office at a cost of \$100 (plus \$10 overseas airmail) and covers the approved terminology for chemical, biological and herbal substances. The new edition is also available in hard copy at a cost of \$175 (plus \$25 for overseas air mail). Please contact the TGA Publications office on 1800 020 653 for further information.

CELLULAR MOBILE PHONES AND CARDIAC PACEMAKERS

The TGA has received a number of queries regarding the safety of implantable cardiac pacemakers under interference from the recently introduced CDMA mobile phone system.

The CDMA mobile phone system, which is a different digital technology to that used in the existing GSM digital system, replaces the existing analogue mobile phones.

Implantable cardiac pacing systems, including implantable pacemakers and defibrillators, are Registrable Devices and are subjected to a high level of scrutiny by the TGA before they are included in the Australian Register of Therapeutic Goods for marketing in Australia.

Manufacturers subject implantable pacing systems to stringent levels of electromagnetic interference testing and samples pass the tests generally with ample safety margins. Testing includes interference from handsets for the various mobile phone systems available worldwide. This information is included in marketing submissions and evaluated by the TGA.

Major pacing systems manufacturers have lately incorporated the CDMA technology as part of these tests. The available information suggests that the immunity of implantable pacing systems to CDMA handsets radiation is comparable or better to that of other digital mobile systems.

It is important to note that implantable pacing systems are designed to 'fail-safe'. Should they be affected by high levels of interference they **temporarily** revert to a safe baseline mode operation.

Some phone handsets incorporate a magnet, either to activate the phone when opened for use or as a part of the loudspeaker in the phone. This magnet, if strong enough, and if held close to the implanted device, can activate the 'magnet' mode of the pacemaker or defibrillator.

The pacemaker does not stop working in this mode, but will pace at a fixed rate.

In any of the cases above **simply moving the phone away from the implanted device will return it to its correct state of operation.**

In summary, it can be said that for mobile phones, including the CDMA handsets, the potential for interference with a pacemaker or implantable defibrillator can be minimised by maintaining a separation of at least 150mm between the handset and the implanted device.

This can be achieved by

- not keeping the phone in a pocket over the site of an implant;
- using the ear which is furthest away from the site of the implant when operating the phone; and
- avoiding direct contact between the phone antenna and the user's skin.

For further information please contact the Device Registration and Assessment Section on phone (02) 6232 8777, facsimile (02) 6232 8785 or E-mail: CAB Medical Device Information@health.gov.au.

UPDATE ON THE REGULATION OF DISINFECTANTS

Following a meeting of the Disinfectant Working Group on 17 December 1999, the TGA is now in a position to amend the Therapeutic Goods Regulations 1990. The proposed amendment would include the shift of hospital grade disinfectants (with specific claims) and household/commercial grade disinfectants with specific claims from the registrable category to the listable category of the Australian Register of Therapeutic Goods (ARTG). Test certificates will be required to support listing for those products making 'specific claims'.

The proposed listable hospital grade and household/commercial grade disinfectant applications making specific claims and those making high level disease claims such as for HIV, tuberculocidal and hepatitis C may undergo a safety assessment in the future.



The Therapeutic Goods (Excluded Goods) Order relating to low risk household/commercial grade disinfectants is expected to be finalised mid year. Industry is in the process of developing a Code of Practice for those products claiming antibacterial action excluded from the TGA's regulatory controls. This will provide a standard practice for sponsors wishing to make claims for goods outside of the TGA's regulatory scope.



IMPORTANT MEDICAL DEVICE TELEPHONE NUMBERS

Medical Device Information Line	1800 020 653
Reporting of a Medical Device Incident	1800 809 361
Recalls	(02) 6232 8636
New Medical Device Legislation	(02) 6232 8576
TGA Publications	(02) 6232 8610
Medical Devices Listing Enquiries	(02) 6232 8048
Medical Device Registration Enquiries	(02) 6232 8613
Medical Device Export Certification	(02) 6232 8671
Australian Register of Therapeutic Goods	(02) 6232 8601
Clinical Trials for Medical Devices	(02) 6232 8615
Applications for Individual Patient Use (IPU)	(02) 6232 8777
Advertising Claims	(02) 6232 8664
Manufacturing issues	(02) 6232 8628

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