

The Australian and New Zealand Medical Device Incident Report Investigation Scheme

What is it? The Scheme is a joint venture between the Australian Therapeutic Goods Administration and Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, intended to help maintain the standard of devices used in health care through voluntary co-operation between users, government and industry. It should be used in conjunction with local reporting channels. It provides an additional means by which unsafe products or procedures can be identified quickly so that appropriate action is taken.

Use this form to report any suspected problems with a therapeutic device which has or may present a health hazard. Reports originating in Australia should be sent to the Therapeutic Goods Administration and reports originating in New Zealand should be sent to the Ministry of Health.

What should be reported? Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. If appropriate both Agencies will assess the issue and it may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following: 1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, efficiency or quality. 2. Therapeutic Device Alert - urgent information to inform those responsible for the device, or affected by the problem. 3. Report in a Therapeutic Device Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical Device Incident Report

Use this form to report any suspected problem with a therapeutic device which may create a health hazard. A therapeutic device is any material instrument, apparatus, machine implement, contrivance, implant etc including any component, part or accessory which is used in health care and includes diagnostic reagents

A. Product Identification *(Provide all available details. Where * appears, delete whichever is not applicable)*

1. Product Type/Application
2. Brand/Trade * Name and Model Number
3. Serial/Batch/Lot * Number
4. Date of manufacture Date of purchase Date of expiry * AUSTL or AUSTR No.
5. Manufacturer's name address and telephone
6. Supplier's name address and telephone
7. Has the manufacturer been informed of the problem? Yes No
If Yes, please supply the date and contact name
8. Is the product/packaging * available for inspection? Yes No *(please do not discard these items)*

Important: Please fill in Sections B and C overleaf

B. Problem Description:

1. Consequences and history of problem:
(please Include history, circumstances, consequences and where relevant sketches or explanatory information)

C. Reporter Identification

Do you want your identity to remain confidential? Yes No

1. Name	<input type="text"/>		
2. Position/ occupation	<input type="text"/>		
3. Dept or Institution	<input type="text"/>		
4. Address	<input type="text"/> <input type="text"/>		
5. Telephone	<input type="text"/>	Facsimile	<input type="text"/>
E-mail	<input type="text"/>	Office Use	<input type="text"/>
Signature	<input type="text"/>	Date	<input type="text"/>

D. Submitting the Form

In Australia:

Reply Paid 32
The Manager
Medical Device Incident Report Investigations
Therapeutic Goods Administration
PO Box 100 Woden ACT 2606
AUSTRALIA

Fax Number: (02) 6232 8555,
E-mail : iris@health.gov.au
Urgent problems may be reported by
telephone to our HOTLINE : 1800 809 361.

In New Zealand:

Compliance Team
Medsafe
Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND

Fax Number: (04) 496 2599,
E-mail : trevor_nisbet@moh.govt.nz
Urgent problems may be reported by
telephone on (04) 496 2364