

Medicines Matter

AN INFORMATION SERVICE FOR PATIENT GROUPS

Volume 6 Issue 1

This issue of **Medicines Matter** provides information on Edition 15 of the Medicines Australia Code of Conduct and details pertaining to the reporting of educational events held or sponsored by a pharmaceutical company.

Code of Conduct

The Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation.

A free copy of the Code of Conduct can be obtained by phoning Medicines Australia on 02 6122 8500.

The Code of Conduct and Guidelines are available from the Medicines Australia website at <http://www.medicinesaustralia.com.au/pages/page16.asp>

Rights

The rights of healthcare professionals, members of the general public and pharmaceutical companies are recognised, including the right to lodge a complaint and the right to an impartial decision. Where anonymity by a healthcare professional or member of the general public to the pharmaceutical company has been requested, this will be respected. However, anonymous complaints to the Secretariat will not be accepted.

The complaints process is free of charge.

Complainants and the Subject Company have the right to appeal a decision of the Code of Conduct Committee. The appeals process is free of charge for non-industry appellants.

Complaints and appeals will be considered in a transparent, equitable, objective and unbiased manner by the Code of Conduct and Appeals Committees. The complaints handling process will reflect the principles of natural justice and procedural fairness.

Accessibility

The complaints process is readily accessible to pharmaceutical companies, healthcare professionals and members of the general public. An 'Independent Facilitator' is available to assist Non-industry Complainants.

Where a complaint falls outside the jurisdiction of Medicines Australia the matter will be referred to the most appropriate alternate body.

Timeframe

The complaints handling process will be responsive and target times for handling complaints have been set down in the provisions of the Code of Conduct. The Complainant and Subject Company will be informed of all decisions and provided with an extract of the minutes pertaining to their particular complaint.

Reports

The outcomes of all finalised complaints are published on the Medicines Australia website in quarterly and annual reports.

Lodging a Complaint

A member of the general public, healthcare professional, academic, Therapeutic Goods Administration (TGA) may lodge a complaint in relation to the activities of, or materials developed by, the Australian manufacturer or sponsor of a prescription medicine.

Information on lodging a complaint can be found on the Medicines Australia website at <http://www.medicinesaustralia.com.au/pages/page34.asp>

Who considers the complaint?

Complaints are reviewed by the independent Code of Conduct Committee.

Members include:

- Trade practices lawyer (Chair)
- 1 consumer
- 3 general practitioners (GPs)
- 1 specialist
- 1 pharmacologist
- 1 person (either a doctor or pharmacist) from the TGA – regulator of medicines in Australia)
- Max. 5 pharmaceutical company representatives (Managing Directors or Medical/Scientific Directors)

Reporting Educational Events

Medicines Australia member companies will report all educational events for healthcare professionals – whether a company educational event or the company sponsored the educational event.

Each Medicines Australia member company is to provide Medicines Australia with a report detailing all events held in a 6 month period:

- 1 July – 31 December
- 1 January – 30 June

Medicines Australia will publish the reports on our website each March and September.

What is an educational event?

These are events where information on a medicine, disease area, illness, clinical data is provided to a healthcare professional:

- Congress – events organised by a college, society, university or other non-company entity
- Symposium – scientific meeting sponsored by a company as an independent event or as a satellite to a congress
- Satellite – meetings held in conjunction with international or Australasian congresses, under the auspice of a non-company entity
- Grand Rounds – a term describing when all the doctors visit all the areas of the hospital together to discuss the patients. These are usually conducted only once per week.
- Journal Club - a group of individuals (usually within a hospital setting) who meet regularly to critically evaluate recent articles in scientific literature.
- In-service – a set of lectures, tutorials or other formalised teaching within the hospital setting.
- Company event - an event organised by a pharmaceutical company for healthcare professionals
- Meeting
- Conference
- Seminar

Who is a healthcare professional?

A person, who in the course of their professional activity prescribes, dispenses or administers a prescription medicine:

- Doctors
- Nurses
- Pharmacists

How will the education event reports appear on the MA website?

The Educational event section of the MA website has been constructed to provide:

- context around the reporting requirements;
- an executive summary of the Auditors report;
- clear pathway to the actual company reports; and
- easily accessible information on the Code and complaints process.

Glossary

A glossary of terms used in the educational event reports will also be provided on the website.

Independent Audit

All company educational event reports have been forwarded to an independent auditor for analysis and compliance with the Code.

Steps in conducting the audit:

- Compile and 'clean' the data;
- Assign unique identifiers;
- reconciliation – ensure no lost data;
- Validation – identify where data missing, incomplete (eg No. hours education), unexpected zero value, cost of function < cost of hospitality;
- Population analysis and establish test thresholds;
- Test against thresholds; and
- Report.

Where will the auditors report go?

- An executive report will be published on the Medicines Australia website;
- A report of all events which fall over the statistical threshold will be forwarded to the Monitoring Committee for review;
- Having reviewed the events the Monitoring Committee may forward events of concern to the Code of Conduct Committee for a determination – whether the event is in breach/not in breach of the Code; and
- Once finalised the outcomes of these complaints will be published on the Medicines Australia website.

What happens if a report is found in breach of the Code?

The Code of Conduct Committee has the power to impose sanctions on a company found in breach of the Code.

Sanctions include:

- Withdrawal of materials found in breach
- Cease an activity found in breach
- Issue a 'Retraction Statement' – corrective letter or advertisement
- Pay a fine – up to \$200,000

Table of Events to be completed by a Medicines Australia Member Company

Summary of Events sponsored by Member Companies: Reporting Period (July – December 2007)

Company Name:

Number of events held:

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
<p>Companies to provide as much information as they feel necessary to explain the educational component</p> <p>For example, type of function, nature of education provided, length of education, CPD/CME points</p>	<p>Specify:</p> <ul style="list-style-type: none"> • Venue name • Location 	<p>Specify:</p> <p>For example</p> <ul style="list-style-type: none"> • Anaesthetists • General Practitioners 	<p>Specify the nature of the hospitality provided and whether it included any of the following elements:</p> <ul style="list-style-type: none"> • Food and/or beverages • Accommodation • Travel • Entertainment 	<p>\$ cost</p> <p>This must state the total cost of the items listed in the hospitality column.</p> <p>A breakdown of those costs may be provided if desired.</p>	<p>XX</p>	<p>\$ cost</p> <p>Including</p> <ul style="list-style-type: none"> • Speaker fees • Venue hire • Transportation costs • Materials specifically developed for and provided to attendees at the educational event etc

Pharmaceutical Benefits Scheme Reform (PBS)

In 2007 the Government made a number of reforms to the Pharmaceutical Benefits Scheme (PBS). These comprise the following:

- changes to the pricing of PBS listed medicines
- pharmacy and pharmaceutical wholesaler
- compensation arrangements
- streamlines authority approvals for some medicines
- establishment of "The Access to Medicines Working Group

Changes to pricing of PBS listed medicines

Since August 1, 2007, PBS medicines will be listed on two separate formularies:

- Formulary 1 (F1) containing single brand medicines (i.e. medicines which only have one brand on the PBS), which are not interchangeable at the patient level with multiple brand medicines (medicines with more than one brand listed on the PBS)
- Formulary 2 (F2) containing multiple brand medicines and any single brand medicines which are interchangeable at the patient level with multiple brand medicines.

Medicines will be classified into only one formulary. There will be no ongoing price links across medicines listed on F1 and those listed on

F2, e.g. price cuts to F2 medicines will not impact the price of medicines listed on F1, however, reference pricing will continue to apply within the F1 and F2 formularies.

Over time, all medicines listed on F2 will move to a system of price disclosure, where the suppliers must agree to disclose the actual market price at which they sell a brand of medicine, as a condition of listing. Staged price reductions for that medicine will then apply until the price of the medicine is based on the disclosed price and the price that the Government pays will more closely reflect the actual price at which the medicine is being sold.

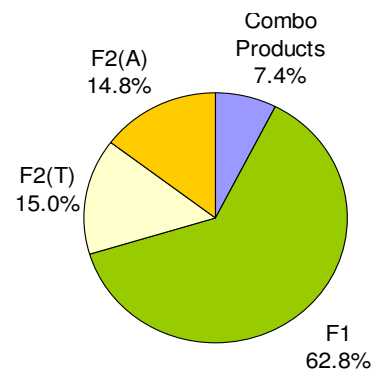
As a transitional measure, the F2 formulary has been split into two parts:

- Formulary 2A (F2A) comprising low competition medicines
- Formulary 2T (F2T) comprising high competition medicines, as determined by the level of discounting the Government believes has been occurring in the market for that medicine.

Since August 1 2007, medicines moving from F1 to F2 can only be classified into F2A. The F2T formulary is, generally, a completed list and no new medicines can be added to that.

Medicines will attract different price reductions depending on whether they are classified into F2A or F2T. From January 1st 2011, however, the pricing arrangements for the F2A and F2T formularies will be the same and they will effectively merge to be simply F2.

Formularies as at September 2007



Price Disclosure

As well as mandatory cuts, more price cuts in the future will be determined by discounting going on in the market for generic medicines.

The Government will price track the actual market price. Medicines Australia supports PBS reform, including disclosure and cheaper generics.

Generic medicines awareness campaign

The government is considering a public awareness campaign to promote the use of generic medicines. The campaign is expected to comprise print, radio and television advertisements, which promote the safety, health and economic aspects of generic medicines. It would focus in particular on high users of the PBS, including concession card holders and those with chronic, long term conditions.

Access to Medicines Working Group (AMWG)

The Working Group comprises Medicines Australia and the Department of Health and Ageing.

AMWG is looking at issues of listing new medicines:

- Streamline processes to list a new medicine on the PBS;
- Impact of PBS reform on the listing process
- The potential for improving data, evidence and transparency for listing;
- Managing uncertainty; and
- Informing and learning from the broader international debate.

What PBS reform means for consumers

- Continued patient access to new medicines in the future
- Potentially ensure that generic price reductions won't delay listing of new therapies in the future
- Quicker listing of medicines on the PBS
- Sustainable PBS
- Lower prices for off patent/generic medicines

More information on these topics is available at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs_reform_02feb07.htm

