

Medicines Australia Code of Conduct Quarterly Report July - September 2015

The quarterly report of determinations of the Medicines Australia Code of Conduct and Appeals Committees

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 18 (Effective 16 May 2015).

This report covers all complaints finalised between April and June 2015. Complaints finalised during this period were in relation to materials or activities conducted under Edition 17 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website <http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/>

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How do I obtain a copy of the Code?

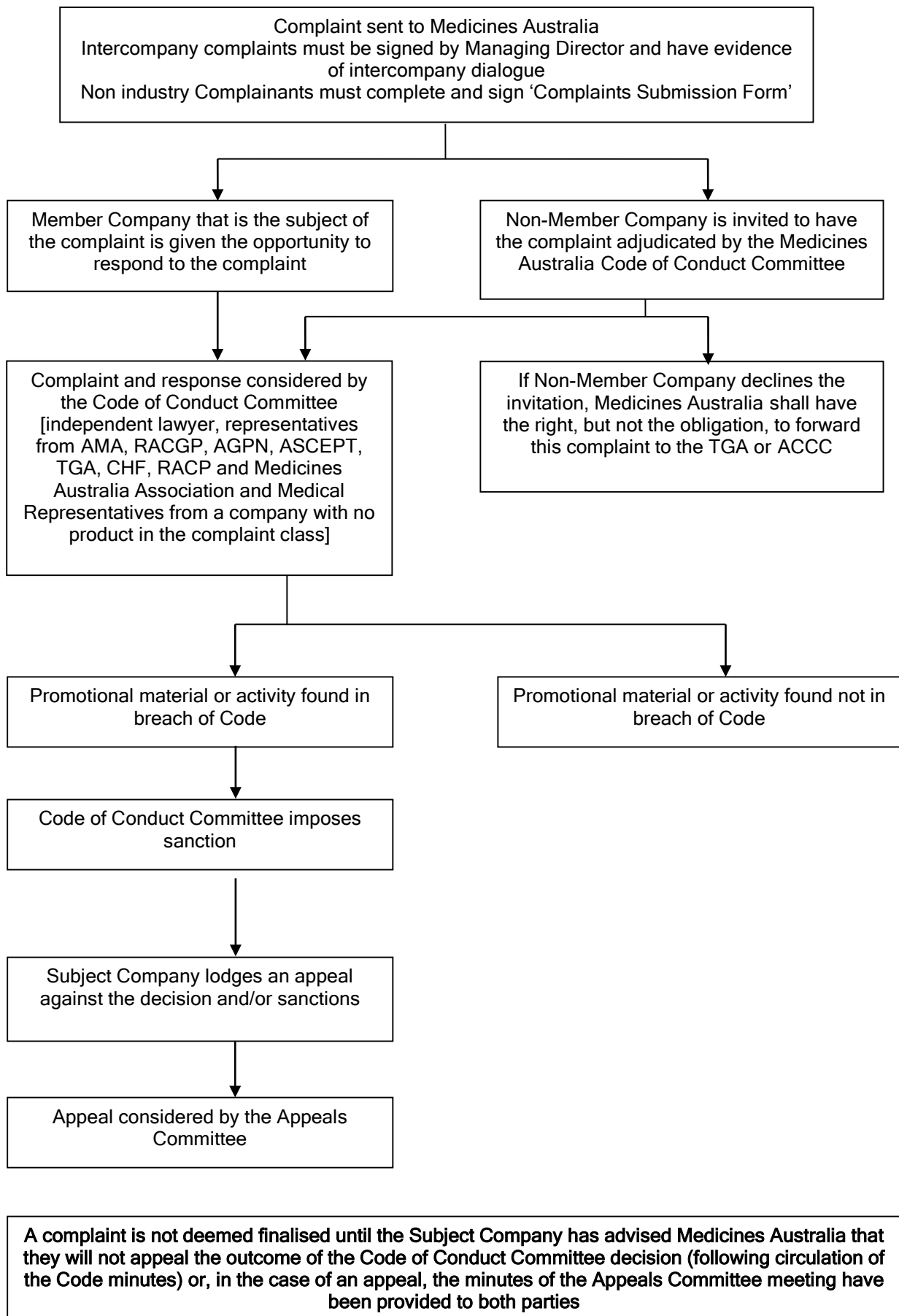
Copies of Edition 18 of the Code (effective from 16 May 2015) are available from Medicines Australia. An order form is available from <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>

The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>)

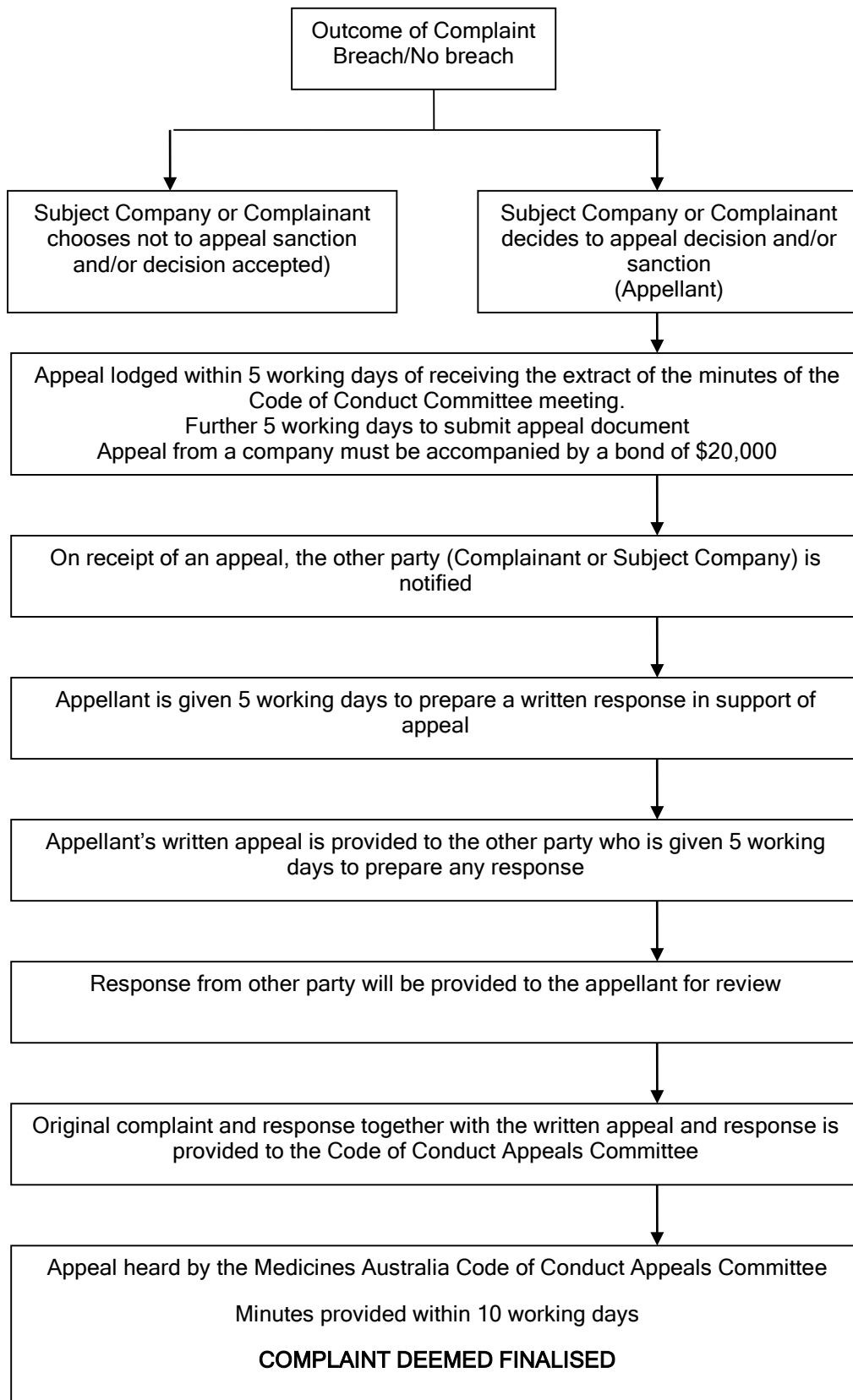
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Medicines Australia Code of Conduct Complaints Handling Process



Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code, and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website <https://medicinesaustralia.com.au/code-of-conduct/committee-membership/>

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- Australian General Practice Network (AGPN)
- Australian Medical Association (AMA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Consumers Health Forum of Australia (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australian College of General Practitioners (RACGP)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Therapeutic Goods Administration (TGA)
- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

- Secretary, Code of Conduct Committee
- Medicines Australia Chief Executive Officer or delegate
- Medicines Australia officer responsible for Scientific and Technical Affairs

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

- Secretary, Code of Conduct Committee
- Medicines Australia Chief Executive Officer or delegate

Sanctions that can be imposed by the Code of Conduct Committee

Sanctions

If the Code of Conduct Committee finds a breach of the Code it may impose a sanction on the company found in breach. In order to determine an appropriate sanction the Committee will refer to the “Guidelines for determining Code sanctions” which are available on the Medicines Australia website. The following sanctions may be imposed:

Withdrawal of material or activity

Where promotional material or activity is found in breach of the Code the Committee will always require the company to cease use of the item or cease undertaking the activity.

Corrective letter

The Code of Conduct Committee will determine the audience for the letter based on the original distribution of the material found in breach of the Code.

Corrective advertisement

A corrective advertisement must be placed in the same publication as that found in breach of the Code.

Fines (applicable under Edition 17 of the Code)

<u>Breach</u>	<u>Fine</u>
Technical breach Minor breach	Maximum of \$100,000
Moderate	Maximum of \$150,000
Severe breach	Maximum of \$200,000
Severe breach where activities completed Repeat of previous breach	Maximum of \$250,000
Cumulative fine for multiple breaches	Maximum of \$300,000
Failure to complete corrective action in 30 calendar days Failure to pay a fine in 30 calendar days	Maximum of \$50,000
Abuse of the Code (in accordance with Section 25)	Maximum of \$200,000

Table of finalised complaints July – September 2015

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1128	Roche Products	Media Communications	Gazyva	Monitoring Committee	Breach of Section 13.4	Pay of fine of \$100,000

1128 – Roche Media Communications

Subject Company: Roche Products Pty Ltd

Complainant: Monitoring Committee

Product: Gazyva

Complaint

Following its review of media releases to the consumer media across all therapeutic classes, the Monitoring Committee had referred activities in association with the publication of a Roche media release announcing the TGA approval of Gazyva to the Code of Conduct Committee.

The Monitoring Committee had considered that the media release relating to Gazyva was consistent with the Code. However, the Monitoring Committee considered that a number of media reports generated by the media relations activities associated with the issue of the media release indicated that Roche had potentially breached the Code of Conduct. The Monitoring Committee was of the opinion that the media reports included statements that would give an unrealistic expectation about the chance of successful treatment for leukaemia. The Monitoring Committee had unanimously agreed to refer the matter to the Code of Conduct Committee for adjudication.

Sections of the Code

The conduct was alleged to be in breach of the following Sections of Edition 17 of the Code:

- 13.4 Relationship with the Consumer Media
- 13.6 Educational Material to the General Public

Response

Roche responded to the complaint, stating that the Monitoring Committee had found the media release to be balanced and it had included an appropriate level of detail on safety and side effects. Roche stated that the media statement had been released in accordance with the Code. Through interactions with an experienced health journalist, who is part of a syndicated news network, and a television journalist, the resultant story was distributed much more broadly than originally intended.

Roche asserted that the media statement was fully compliant with the Code. All briefing

documents and contracts with healthcare professional and patient spokespeople were appropriate and had been suitably reviewed and approved by Roche. Whilst some of the patient's descriptions of his experience to the journalist were emotive, Roche's briefing of the agency and the agency's briefing of the patient were compliant with the Code and the company's policies.

Roche further argued that the media is independent and resulting reportage cannot be controlled by companies.

Code of Conduct Committee decision

The Committee agreed in a unanimous decision that the conduct subject to complaint was in breach of Section 13.4 of the Code of Conduct.

The Committee agreed in a majority decision that the conduct subject to complaint was not in breach of 13.6 of the Code of Conduct.

Sanction

The Committee determined that the breach was moderate as defined by the Code.

The Committee determined by majority decision that Roche must pay a fine of \$100,000. Roche, its employees or personnel for whom Roche is responsible must not repeat the same or similar conduct as that found in breach of the Code.

Consideration of the complaint

The Committee reviewed the media reports, which resulted from the media relations activities conducted by Roche employees and personnel for whom Roche was responsible, the healthcare professional's and patient's briefing information and agreements, and the Gazyva consumer media statement.

The Committee agreed with the Monitoring Committee that the resulting media reports, which were numerous and widely published, were overly optimistic about the likely outcomes from treatment with Gazyva and may have the effect of encouraging people with leukaemia to seek treatment with the product.

The Committee considered Roche's conduct relating to these reports. The Committee noted that sections 13.4.4 and 13.4.5 state that a company is responsible for its employees and agents in relation to interactions with the general media, and is responsible for any material prepared for the media by its agencies

and for healthcare professional and public citizen spokespeople. The Committee confirmed that the matter for its consideration is whether Roche has breached the Code of Conduct.

The Code Committee noted that Roche did have agreements in place with both the healthcare professional quoted in the media release and the patient quoted in the media articles. The terms of the agreement between Roche and the patient spokesperson referred to Roche adhering to the Therapeutic Goods Act and the Code of Conduct. Whilst the agreement states that Roche may not provide promotional information to the public, the agreement was not sufficiently clear to the patient spokesperson regarding what they may or may not say to the media when interviewed. The Committee acknowledges that this information may have been imparted in a verbal briefing provided to the patient spokesperson in conjunction with the written agreement. The Roche patient agreement also states that a patient “may express your own opinion and discuss your experiences with medicines as you choose. When sharing your story or responding to questions about treatments, we ask that you provide balanced and factual information”. This indicated to the patient that they may speak to the media about their drug treatment outcomes, including positive outcomes. The Committee accepted that there is a tension between providing an independent view from a patient spokesperson and a company seeking to control what a patient says. However, a company is responsible for ensuring that a patient spokesperson is fully briefed on the Commonwealth Therapeutic Goods Legislation and the Code of Conduct in particular that prescription products must not be promoted to the general public.

The Committee further noted that Schedule One to the Letter of Agreement between Roche and a healthcare professional spokesperson referred to the healthcare professional identifying a patient who is being treated with Gazyva and “is experiencing a good response” for media interviews. The Committee considered that this indicated that it was Roche’s intention that the patient case study would communicate positive outcomes from Gazyva through generating media stories.

The Committee reviewed an email from a person for whom Roche was responsible to the syndicated journalist who reported on the availability of Gazyva. The email offered the

journalist a “strong patient case study” for a patient who would have died without the treatment. The email referred to the patient now being able to ride long distances on a mountain bike, which was reported in the media articles. The Committee noted that in its response to the complaint Roche had stated that the email had included information on the patient’s diagnosis, treatment and recovery, some of which Roche considered was inappropriate. Other statements in published media articles about the effectiveness of the product in destroying cancer cells and the patient’s personal experience from his treatment were attributed directly to a healthcare professional spokesperson and the patient, evidently following their interviews with the journalist.

The consumer media reporting of the availability of Gazyva primarily occurred on 27 and 28 October 2014. In this reporting there were a number of statements about the patient’s positive outcome from treatment with Gazyva, including statements attributed to the patient himself. These statements promoted Gazyva to the general public.

The Committee agreed with the Monitoring Committee that the consumer media release dated 27 October 2014 was consistent with the Code. However, Section 13.4 relates to all communications with the media by the company, its employees and agents, not solely a media release. The Committee unanimously determined that the interactions between Roche, its employees and people for whom the company was responsible and the consumer media were in breach of Section 13.4 of the Code because the product specific media release was accompanied by the abovementioned email which

- a) was material which encourages or is designed to encourage the use of a prescription product; and
- b) had a purpose which was not solely educational and informative

and therefore in breach of Section 13.4.3.

The Committee discussed whether Section 13.6 was relevant to the conduct subject to complaint. Section 13.6 relates to educational material available to the general public. The Code Committee noted that initially the Monitoring Committee had questioned whether educational information in addition to the media release had been distributed by Roche or other personnel for whom the company was responsible. Roche had clarified that no other educational information had been distributed

with the media release. Some members of the Committee nevertheless considered that Section 13.6 did apply to the conduct subject to complaint because information communicated to the general public through the media activities was not balanced and had the potential to raise unrealistic hopes of successful treatment with Gazyva. However, a majority of the Committee considered that the conduct subject to complaint more properly came within the scope of Section 13.4 - Relationship with the Consumer Media. In a majority decision, the Committee found no breach of Section 13.6.

The Code of Conduct Committee commented that this was a complex matter and it would have assisted the Committee to have received a more detailed and specific explanation of the Monitoring Committee's concerns.

Sanction

Having found the media activities to be in breach of the Code, the Code Committee discussed the severity of the breach. The Code Committee agreed unanimously that the breach was moderate as defined by the Code.

The Code Committee agreed by majority decision that:

- Roche must pay a fine of \$100,000
 - Roche, its employees or personnel for whom Roche is responsible must not repeat the same or similar conduct as that found in breach of the Code.
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