Medicines Australia Code of Conduct Quarterly Report April – June 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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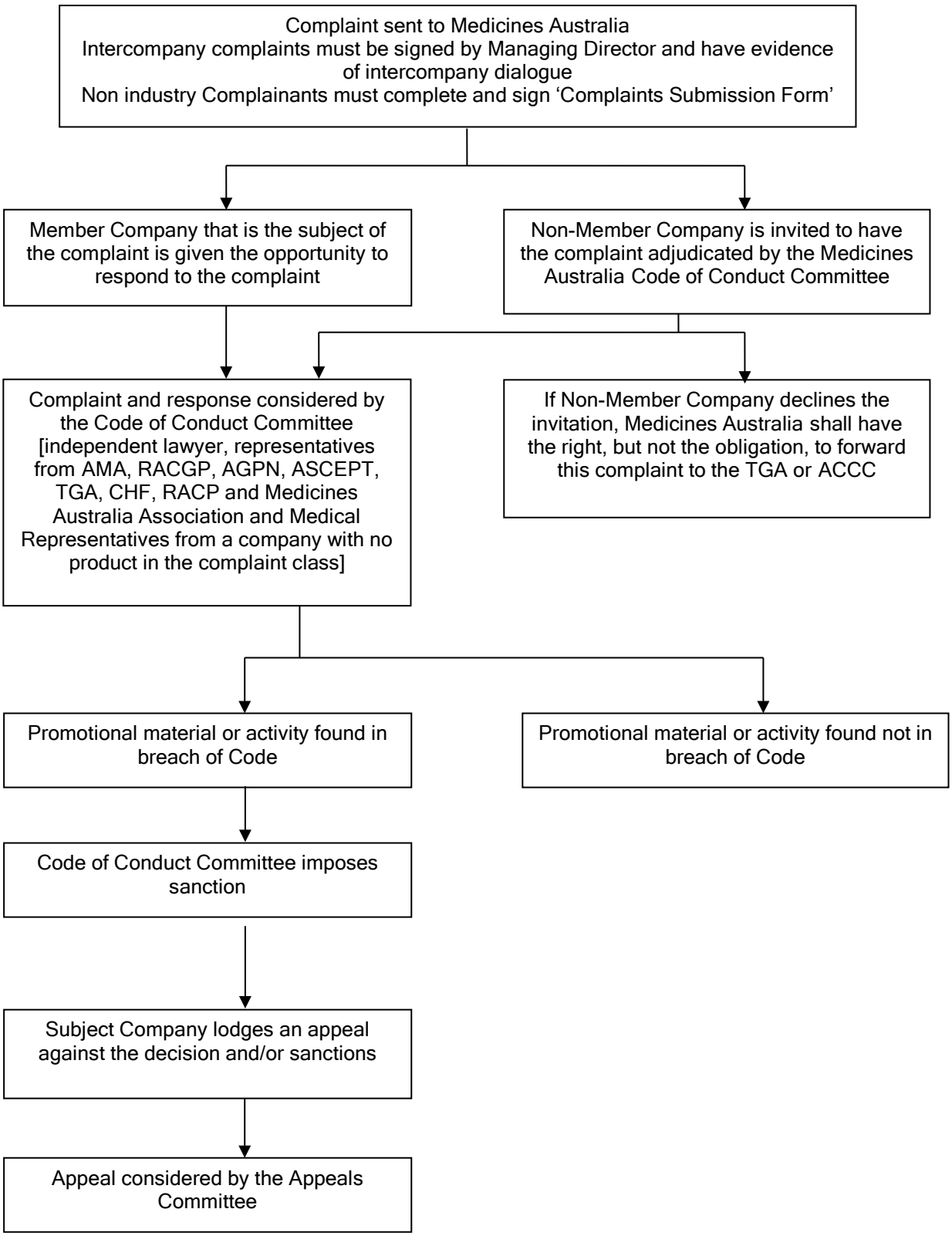
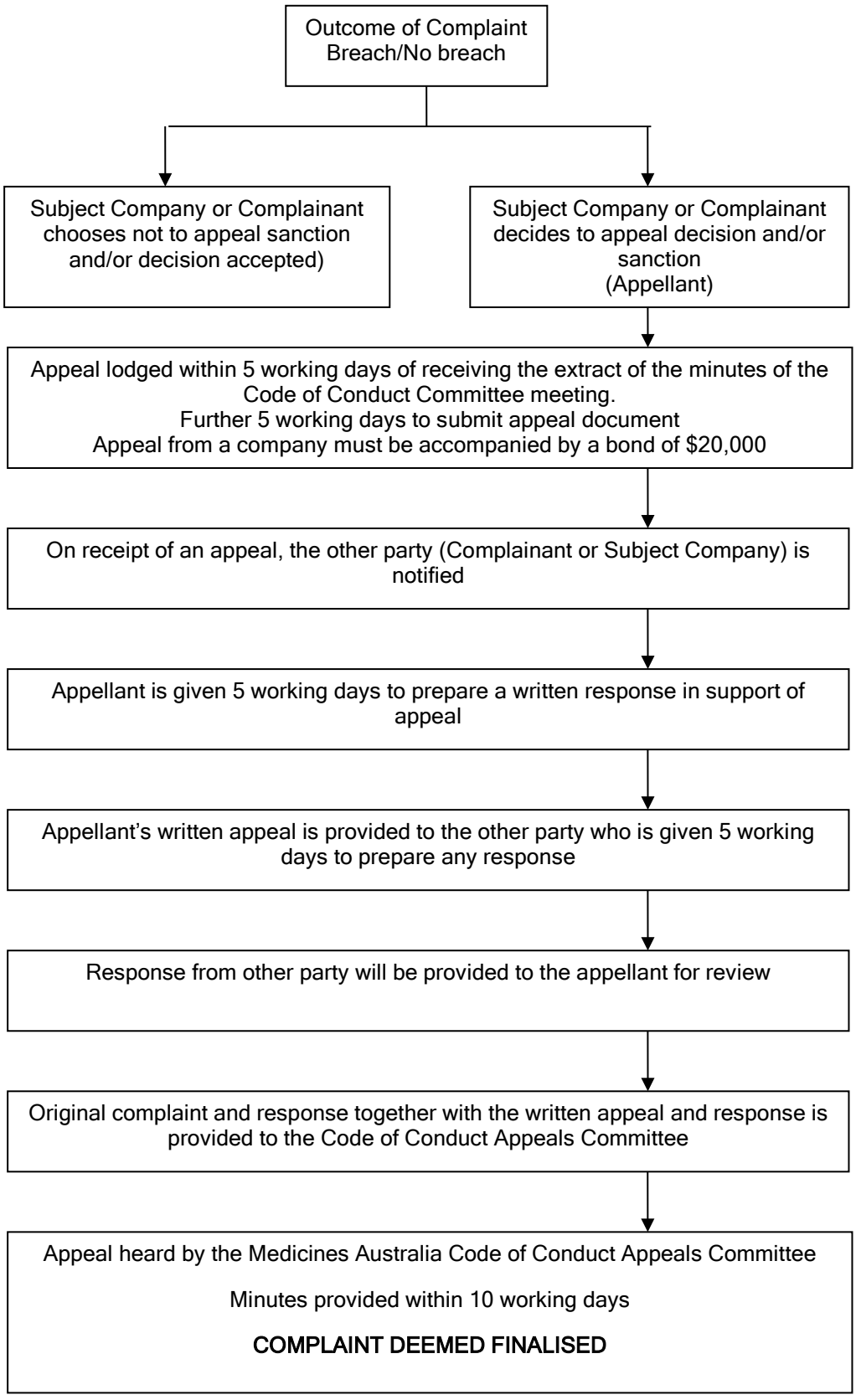
Medicines Australia Code of Conduct Complaints Handling Process



A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties

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)

Breach	Fine
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 April – June 2015

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1127	Novartis Pharmaceuticals	Media Release	Ultibro Breezhaler	Monitoring Committee	Breach of Section 13.4.1	Pay of fine of $30,000

1127 – Ultibro Breezhaler Media Release

Subject Company: Novartis Pharmaceuticals Australia Pty Ltd

Complainant: Monitoring Committee

Product: Ultibro Breezhaler

Complaint
Following reviews of media releases and disease education activities to the general public, the Monitoring Committee believed that a media release issued by Novartis had potentially breached the Code of Conduct, and unanimously agreed to refer the matter to the Code of Conduct Committee for adjudication. The Monitoring Committee were of the opinion that the media release for Ultibro Breezhaler 110/50 contained promotional claims, specifically statements made by the Key Opinion Leader and included in the media release.

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

- 1.8 Comparative Statements
- 13.4.1 Product Specific Media Statements

Response
Novartis asserted that the statement by the Key Opinion Leader was not included with the intention of being promotional to the general public, and should not be read in isolation from the information surrounding it. Novartis defended its position stating that the inclusion of two compounds in a single device could reasonably be considered a "step forward" by patients and clinicians because of the potential for improved compliance. Novartis believes that when taken in context of the previous paragraphs, the Key Opinion Leader statement simply captures that fact.

Code of Conduct Committee decision
The Committee agreed by unanimous decision that the media release was in breach of Section 13.4.1 of the Code of Conduct. The Committee also agreed by unanimous decision that Section 1.8 of the Code did not apply to a media release directed at the general (consumer) media and was therefore not considered in relation to this complaint.

Sanction
Having found that the media release was in breach of the Code, the Committee imposed the following sanctions:

- Pay a fine of $30,000.
- Novartis must not use the statement found in breach of the Code in any future activities directed at the general public;
- If the media release is available on the Novartis Australia corporate website, Novartis must remove it.

Consideration of the complaint
The Chairman summarised the complaint for the Code Committee. He noted that the Monitoring Committee had reviewed two media releases for Ultibro Breezhaler; one of which was directed at Healthcare Professional media and the other to general (consumer) media. The media release subject to complaint was the latter.

In its deliberations about the complaint, the Code Committee noted that the Monitoring Committee had proposed that the media release to the consumer media was potentially in breach of Section 1.8 of the Code. The Code Committee noted that Section 1.8, Comparative Statements falls under Code Section 1: Educational and Promotional Material Directed at Healthcare Professionals. It therefore did not apply to a media statement directed to the consumer media. However, Section 13.4.1 of the Code prohibits the inclusion of comparisons with other products in product-specific media statements for the consumer media because such statements would be considered promotional. The Committee agreed unanimously that Section 1.8 did not apply to the Ultibro Breezhaler media statement to the consumer media.

The Code Committee noted that the Monitoring Committee's complaint centered on the statement *"combining the treatments in one single device is a key step forward in disease management"*, and whether this statement was a claim or not. The Code Committee agreed that the use of the words "*key step forward*" inferred superiority of the combination product and that the combination of the two products into a single device was new and more efficacious in patients with COPD. The Code Committee agreed unanimously that this statement was a promotional claim for the Ultibro Breezhaler.

The Code Committee considered whether the statement could be considered to be comparative. It noted that there were other

combination products registered in Australia for the treatment of COPD at the time the media statement was issued. The Code Committee acknowledged that the other combination products were for severe COPD, whereas the Ultibro Breezhaler was approved for use in less severe COPD. However, the Code Committee agreed that the statement could be interpreted as comparing the new combination inhaler with existing inhalers used to treat COPD. The Code Committee further noted that the statement, which referred to "*combining the treatments*" (underlining added) mentioned in the preceding paragraph, could be interpreted to be a comparison with the single ingredient inhalers now combined in the new inhaler. With either interpretation, the statement was determined to be a comparative statement.

The Committee further noted that the references supplied by Novartis showed that patients on multiple single product inhalers had lower adherence to their treatment regimen than those on combination inhalers. The Committee considered that without specific evidence to support it, the inverse – better adherence to combination inhalers – cannot be assumed. However, the question of whether the claim could be substantiated was not relevant to the principal matter before the Committee – whether the media release complied with Section 13.4.1 of the Code.

The Code Committee considered the requirements of Section 13.4.1 of Edition 17 of the Code of Conduct and noted that "*Media releases must be educational and not include promotional statements or claims, or comparisons with other products*". The Committee agreed unanimously that the statement attributed to the Key Opinion Leader was a promotional claim and that it was a comparative statement. The media release was therefore in breach of Section 13.4.1 of the Code.

The Code Committee noted that in its response to the complaint, Novartis had stated that it had not included the statement in the media release with the intention of being promotional. However, the Code Committee agreed that the intent of the statement was not relevant; the question for the Code Committee was whether the media release was objectively promotional and whether a reasonable member of the audience to whom it was directed would be likely to interpret it as promotional. The Code Committee determined that the statement was promotional and would likely to be interpreted as such by a reader.

The Code Committee also noted that while not specifically raised by the Monitoring Committee, the statement that the Breezhaler device had been "*specifically designed for use with people who have limited airflow*" was also potentially promotional. The Committee cautioned Novartis to take greater care to avoid promotional statements in materials for the general public.

Sanction
Having found the media release 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 minor, as there was no safety implication for patients and it was unlikely to influence the prescribing habits of healthcare professionals.

The Code Committee agreed unanimously that:

- Novartis must pay a fine of $30,000
- Novartis must not use the statement found in breach of the Code in any future activities directed at the general public
- If the media release is available on the Novartis Australia corporate website, Novartis must remove it.