Medicines Australia Code of Conduct Quarterly Report October - December 2013

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 17 (Effective 11 January 2013).

This report covers all complaints finalised between October and December 2013. 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 17 of the Code (effective from 11 January 2013) are available from Medicines Australia. An order form is available from http://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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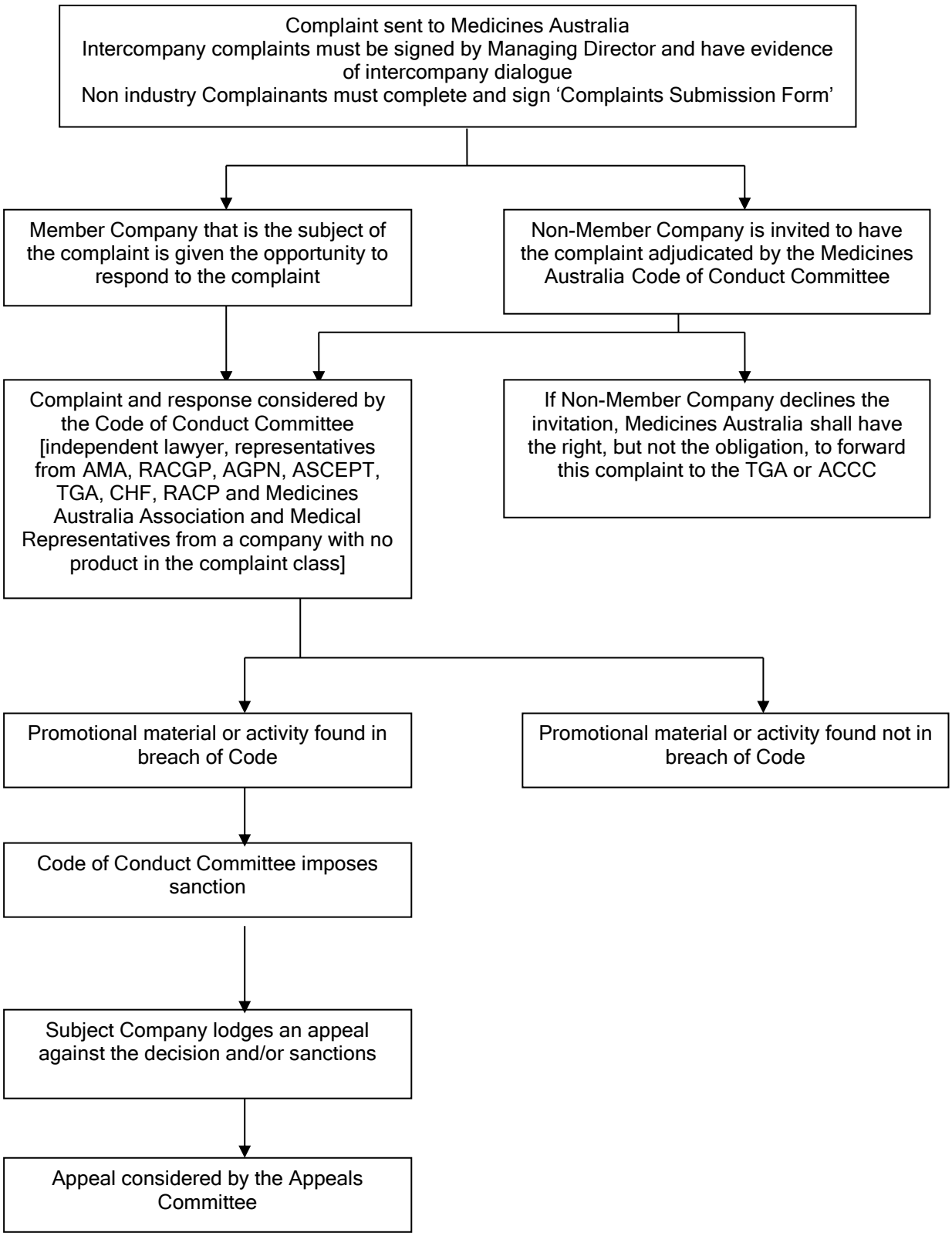
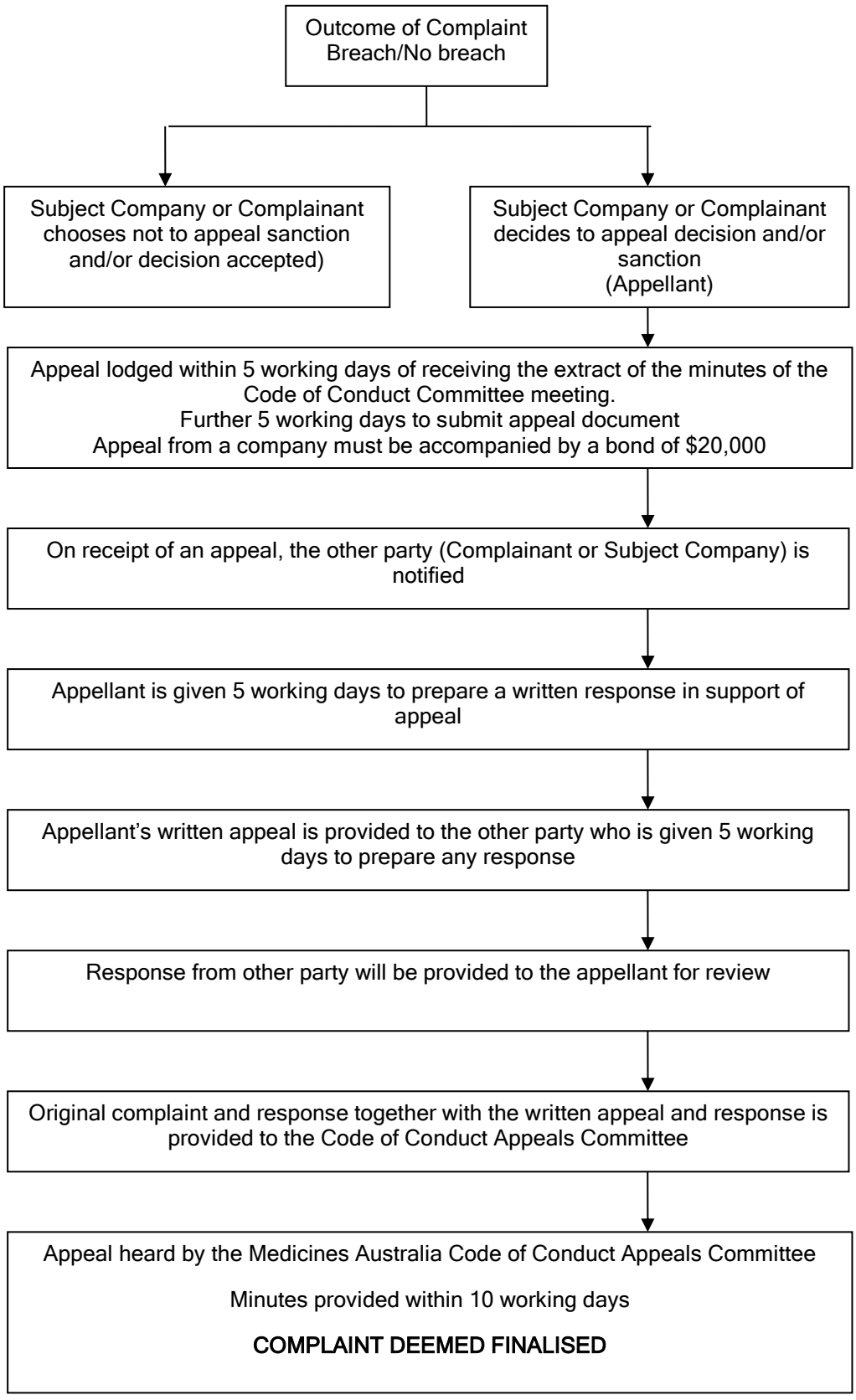
Medicines Australia Code of Conduct Complaints Handling Process



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 http://medicinesaustralia.com.au/code-ofconduct/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, AGPN
- 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.

Fine (applicable under Edition 16 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

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 October – December 2013

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1103	Roche Products	Promotional Material	Actemra	AbbVie Pty Ltd	Breach of Section 1.4	Pay a fine of $15,000
1104	Novartis Pharmaceuticals	Representative Conduct	n/a	Biogen Idec Australia Pty Ltd	No breach found	n/a
1107	Leo Pharma	Educational Event	n/a	Monitoring Committee	No breach found	n/a
1108	Bayer Australia Limited	Promotional Material	Xarelto	Prizer Australia/ Bristol-Myers Squibb Australia	No breach found	n/a

1103 – Actemra Promotional Materials

Subject Company: Roche Products Pty Ltd

Complainant: AbbVie Pty Ltd

Product: Actemra

Complaint
AbbVie alleged that promotional displays for Actemra used during the Australian Rheumatology Association Scientific Meeting in May 2013 had breached the Code of Conduct. Specifically, AbbVie asserted that the claim *"ACTEMRA superior to Humira as RA monotherapy"* was false and misleading.

Sections of the Code
The promotional materials were alleged to be in breach of the following Sections of Edition 17 of the Code:

- Section 1.1 Responsibility
- Section 1.2 Substantiating Data
- Section 1.3 False or Misleading Claims
- Section 1.4 Unapproved Products and Indications
- Section 1.8 Comparative Statements

Response
Roche asserted that the claim communicates an important message to rheumatologists about ACTEMRA and is supported by the head-to-head ADACTA study. Roche denied that the claim breached the Code of Conduct.

Code of Conduct Committee decision
The Committee agreed:

- By majority decision that the material did not breach Sections 1.1, 1.3 or 1.8;
- By unanimous decision that the material did not breach Section 1.2; and
- By majority decision that the material was in breach of Section 1.4.

Sanction
The Committee agreed by unanimous decision that the claim found in breach must not be used in the same or similar form in any future materials without appropriate qualification. The Committee also agreed by unanimous decision to impose a fine of $15,000.

Consideration of the complaint
The Committee noted that the complaint originally concerned two claims that were used by Roche Products at the Australian Rheumatology Association (ARA) Scientific Meeting (18-22 May 2013). Of the two issues, one was resolved during intercompany dialogue between the two companies. AbbVie's concerns regarding the claim *"Actemra, superior to Humira as RA Monotherapy"* remained unresolved.

The Committee noted that the claim *"Actemra, superior to Humira as RA Monotherapy"* was referenced to the study *Tocilizumab monotherapy versus adalimumab monotherapy for treatment of rheumatoid arthritis (ADACTA): a randomised, double-blind, controlled phase 4 trial* by Gabay et al, 2013 published in the Lancet on 4 May 2013. The Committee agreed that the study was well-designed and conducted and had been designed to demonstrate superiority. The Committee agreed that while it was the only head-to-head study comparing Actemra and Humira, it was an appropriate study to use as a

reference for the claim. A minority of the Committee expressed a concern that only one study could be seen as reflecting the body of evidence, but agreed that on balance it was a high quality, well-conducted study which had been published in a well recognised peer-reviewed journal. Therefore the Committee agreed unanimously that the claim did not breach Section 1.2 of the Code.

The Committee noted that there were two versions of the Actemra Product Information provided in the agenda papers. One was dated 19 December 2011 and the other was dated 1 July 2013, which post-dates the ARA Scientific Meeting at which the promotional materials were displayed. The updated Product Information included the ADACTA study, which was the reference for the claims on display at the ARA meeting. The inclusion of the study data in the updated Product Information gave the Committee further evidence for the suitability of the study as a reference for any claims.

The Committee agreed that the product can only be prescribed under the PBS by a rheumatologist and that patients must have demonstrated intolerance to methotrexate before prescribing Actemra as monotherapy. Some of the Committee were concerned that the claim in question did not clearly indicate that Actemra as monotherapy should only be used in patients who have tried therapy with methotrexate but have been unable to tolerate the methotrexate. The Committee noted that the indication for Actemra states (in both versions of the Product Information included in the agenda papers) *"…for the treatment of moderate to severe active rheumatoid arthritis in adult patients… as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate"*. The Committee agreed by majority decision that the claim should have been further qualified to limit the use of Actemra as monotherapy to patients who are unable to tolerate methotrexate or in whom methotrexate is inappropriate. The Committee agreed by majority decision that the claim was in breach of Section 1.4 of the Code.

The Committee noted that the registrants at the ARA Scientific Meeting are specialist rheumatologists who would have a high level of knowledge about prescribing biologic agents for rheumatoid arthritis and that these drugs should be used in combination with methotrexate. The majority of the Committee considered that the specialist audience would not be misled by the claim. A minority of the Committee were concerned that the claim was misleading because it was not sufficiently qualified to limit prescribing as monotherapy only in those patients who could not tolerate methotrexate or in whom methotrexate was inappropriate. The Committee agreed by majority decision that the claims was not in breach of Sections 1.1 or 1.3 of the Code.

The Committee considered whether the comparison of Actemra with Humira as monotherapy in rheumatoid arthritis was fair and not misleading. As already noted, the Committee considered that the study was of high quality and was an acceptable basis for the claim. The study used a well-validated and widely used outcome measure in this therapeutic area – the disease activity score (DAS) – which covers both clinical and symptomatic measures. The study was a head to head comparison between Actemra and Humira, which, although it is the

only head to head study between these drugs, has been evaluated by the TGA and included in the Actemra Product Information. A minority of the Committee were concerned that a single head to head study was not sufficient to make a strong comparative claim of superiority. The Committee concluded by a majority decision that the claim made a fair and justifiable comparison and was therefore not in breach of Section 1.8 of the Code.

Sanction
The Committee agreed that this was a minor breach of the Code. It would have no safety implications for patients' wellbeing and would have no major effect on how the profession would prescribe the product.

The Committee discussed corrective action. It was agreed that as this complaint concerned a trade display at a conference which was attended by specialist rheumatologists it was not appropriate to undertake corrective action in this instance. The Committee did agree, however, that the claim must be withdrawn and not used again in any future materials without appropriate qualification.

The Committee agreed by unanimous decision to impose a fine of $15,000.

Appeal
AbbVie appealed the decisions of the Code Committee to find no breach of Sections 1.1, 1.3 and 1.8 of the Code in relation to the claim "Actemra superior to Humira in RA Monotherapy". AbbVie believes that the Code Committee gave insufficient consideration to AbbVie's arguments that the claim is for outright superiority and that it goes beyond the supporting evidence. AbbVie requested that the Appeals Committee reconsider this in detail.

Appeal Response
Roche does not consider that the Code Committee erred in its decisions by finding that the claim did not breach Sections 1.1, 1.3 and 1.8. Roche considers that the claim of superiority is appropriately qualified, is consistent with the body of evidence and was not in breach of the Code.

Appeals Committee decision
The Appeals Committee agreed by unanimous decision that the appeal by AbbVie was not upheld. The Appeals Committee unanimously confirmed the decisions of the Code of Conduct Committee.

<u>Sanction</u>
As the Appeals Committee confirmed the finding of no breach of the Code in relation to Sections 1.1, 1.3 and 1.8, it did not impose any additional sanction.

Consideration of the Appeal
Prior to consideration of the appeal, the Chairman called for the declaration of any potential conflicts of interest.

The Chairman explained the process for consideration of an appeal to both the Complainant and Subject Company, noting that an appeal is a re-hearing of the original complaint. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error on the basis of which the decisions of the Code of Conduct Committee should be set aside or varied.

The Chairman then invited the AbbVie to make its presentation to the Appeals Committee. The following summarises that presentation:

AbbVie commenced its presentation clarifying to the Appeals Committee the areas of the complaint that are not subject to the appeal. Specifically, AbbVie did not question or appeal the following:

- the quality of the ADACTA study;
- the superiority design or choice of primary endpoint;
- the study results or level of evidence;
- the authors' interpretation or conclusions;
- the interest or validity of communicating this information to HCPs; or
- the relationship between ADACTA and the body of evidence.

AbbVie reiterated that the appeal relates to the claim only, not to the reference being used to support it. AbbVie believe that the claim *"Actemra superior to Humira as RA monotherapy"* is not representative of the conclusions of the ADACTA study. The conclusion of the ACTACTA study noted *"…tocilizumab monotherapy was superior to adalimumab monotherapy for reduction of signs and symptoms of rheumatoid arthritis"*. AbbVie stated that if the claim used on the Roche trade display at the Australian Rheumatology Association Scientific Meeting in May 2013 had been linked to that conclusion, no complaint or appeal would have been lodged. However, AbbVie remain concerned that the claim was for outright superiority of Actemra compared with Humira (in rheumatoid arthritis (RA) monotherapy), without acknowledgement that the superiority was limited to the reduction of the clinical signs and symptoms of RA, and was not superiority on all clinical markers.

AbbVie noted that the reasons for the decision of the Code of Conduct Committee on 19 August 2013 outlined the Code Committee's rationale for finding no breach in relation to the claim under Section 1.2 of the Code. However, AbbVie considered that the Committee's reasons for dismissing the alleged breaches of Sections 1.1, 1.3 and 1.8 were not set out in the reasons for the decision. For this reason, AbbVie seek a review of the decisions from the Appeals Committee. Specifically, AbbVie seek consideration on the following four questions it believes are relevant to the decision:

1) Is it fair and justified to make an outright claim of superiority?
2) Is that claim justified on all relevant aspects of comparison?
3) Does the implied benefit go beyond the study conclusions?
4) Is the use of the qualifier appropriate?

AbbVie believes that it is not justified to make an outright claim of superiority. Such a strong claim should be able to be justified for all relevant comparisons for both efficacy and safety. Specifically, as there is no clinical outcome parameter defined in the claim, a reader would assume it included all relevant elements of comparison. AbbVie argued that there are four relevant elements for comparison – clinical signs and symptoms; Disease Activity Score (DAS28); physical function; and radiographic progression. These four elements of comparison are supported by the body of evidence, and are adopted in Australian and international clinical guidelines. It is AbbVie's view that while the ADACTA study does show a clinical difference between the products, it does not show a statistically significant difference for physical function or radiographic progression. It is therefore AbbVie's

opinion that the claim implies a benefit beyond the conclusions of the ADACTA study and beyond the body of evidence. In relation to safety, there is no evidence of Actemra superiority in the ADACTA study.

AbbVie noted that in its responses to the complaint and the appeal, Roche had relied heavily on the argument that the claim and the qualifier should be seen as a whole. AbbVie are of the opinion that the use of the qualifier itself is at odds with the Code. AbbVie drew the Appeals Committee's attention to Figure 1 in the Code of Conduct Guidelines (version 3, page 14). AbbVie noted that applying this flowchart to the claim in question, the claim should not have been used. The flowchart suggests that a claim should be looked at in isolation to ensure that it is fair, balanced and accurate prior to the consideration of whether it requires a qualifying statement.

AbbVie reiterated its arguments as to why it believes the claim does not meet the standards for being fair, balanced and accurate; and specifically that AbbVie believes it does not reflect the study conclusion accurately. It is AbbVie's opinion that by omitting the outcome parameter in the claim, it does not reflect the body of evidence and therefore is not balanced, accurate or correct. AbbVie contends that an incorrect claim should not be corrected by use of a qualifier.

AbbVie noted that Section 1.8 of the Code states that comparative claims must be substantiated with respect to all aspects of efficacy and safety. However, as already stated, AbbVie considers that the ADACTA study does not provide evidence of superiority for physical function or radiographic progression. The study also does not provide evidence of superiority based on safety.

AbbVie closed its presentation to the Appeals Committee by reinforcing that if the claim had been limited to the conclusions of the authors of the ADACTA study and the clinical evidence, no complaint or appeal would have been made. However, AbbVie contended that Roche used a much more ambitious claim of outright superiority, which did not meet the requirements of the Code of Conduct. AbbVie argued that the Code Committee had not considered these matters.

Roche representatives then made their presentation to the Appeals Committee.

Roche opened its presentation by noting that the question at the heart of this complaint should not be what wording AbbVie would like to see in the claim, but whether the wording Roche used in the claim was correct. Roche contended that it is.

Specifically, Roche noted that the claim and the qualifier were clearly visible and should be read together, and therefore the claim is compliant with the Code. Roche believes that the Code Committee made the correct decisions at its meeting in August 2013.

Roche described for the Appeals Committee the body of evidence that led to its decision to make the claim. The ADACTA study was specifically designed to test whether Actemra is superior to Humira as monotherapy in RA, noting that the entire patient population of the ADACTA study was within the TGA indication for Actemra. ADACTA was published in the Lancet in May 2013, and the Code Committee

had noted it was of high standard and was an acceptable basis for the claim. The ADACTA study showed a statistically significant difference in the DAS28 disease parameter, which was the primary endpoint of the study, and this was supported by secondary endpoints. The DAS28 score is a widely used outcome measure in both studies and clinical practice and it is considered best practice to use for patient assessment. Roche also noted that the TGA approved Actemra on the basis of signs and symptoms based on DAS28. TGA did not require radiographic progression data to approve the product.

Roche contended that the claim highlights the superiority of Actemra over Humira, and the qualifier identifies the study to support the claim. Roche reinforced the Code Committee's reasoning that the specialist audience at the Australian Rheumatology Association Scientific Meeting would not be misled by the claim. The claim reflects the body of evidence and accurately reflects the conclusions of the study. The claim and the qualifier should be read together; the qualifier appropriately limits the claim.

Roche disagreed with AbbVie's interpretation of Figure 1 in the Code of Conduct Guidelines (version 3, page 14). Roche believes that the claim met the requirements of that chart with inclusion of an appropriate qualifier. Roche further noted that there is no provision in the Code of Conduct that requires that a comparative statement must encompass every aspect of the two products being compared. It is Roche's interpretation that if superiority is claimed, then it must be substantiated, but there is no requirement for each and every aspect of a comparison to be superior for the claim to be compliant. Furthermore, Roche believe that the comparative statement it used accurately reflects the ADACTA study, as well as the broader body of evidence in a technically correct manner.

Roche supported its argument by providing examples of comparative statements being used by Medicines Australia members in current advertisements. Additionally, Roche highlighted a recent decision by the Code and Appeals Committees regarding promotional materials for Eylea (Eylea Promotional Materials, Complaint 1092). In this matter, both Committees concluded that the claim and qualifier should be read in conjunction, and not as two separate statements.

One Committee member queried Roche as to whether this claim had been used in any other arenas, for example with general practitioners. Roche confirmed that it had only been used at the Australian Rheumatology Association Scientific Meeting, and it is their intention for it to remain specifically for a specialist rheumatologist audience and not for general practice.

Roche concluded its presentation by stating that the claim is consistent with Sections 1.1, 1.3 and 1.8 of the Code and the Code Committee did not err in its decision in August 2013.

AbbVie was then invited to respond to the Roche presentation and make any closing remarks.

AbbVie reiterated to the Appeals Committee that its appeal is not about the quality of the reference, but the claim itself and that it differs from the conclusions in the ADACTA study. AbbVie further emphasised that a

qualifier should not be used to correct an incorrect claim.

AbbVie believe that the issues it raised in its appeal were not addressed in the Code Committee's reasons for decision and appreciated the opportunity to have the matter reconsidered by the Appeals Committee.

One Committee member noted that Roche had provided a number of examples of other claims currently used in advertisements in the healthcare professional media, and questioned AbbVie as to whether it sees a role for a qualifier in clinical claims. AbbVie responded that the examples used by Roche were not direct comparisons or claims of superiority; none of the examples were a correction of the claim through the qualifier. It is AbbVie's opinion that a claim of superiority should be restricted to the aspect of superiority and the claim itself should stand on its own. AbbVie considers that the claim for Actemra was a bold statement of outright superiority.

One Committee member queried AbbVie's reliance on Figure 1 of the Code of Conduct Guidelines (version 3, page 14) specifically noting that the Guidelines are to be read in conjunction with the Code of Conduct and that the provisions of the Code prevail. AbbVie acknowledged that fact, however noted that both documents should be used to assess the suitability of a claim or promotional item.

The Chairman thanked both companies for their presentations to the Appeals Committee. The representatives from AbbVie and Roche then left the meeting to allow the Appeals Committee to make its decision.

The Appeals Committee agreed that the Code of Conduct did not differentiate between types of comparative claims. The requirements are no different for a claim of superiority from any other type of comparative claim. The Appeals Committee agreed that AbbVie had interpreted the flowchart at Figure 1 of the Code of Conduct Guidelines (version 3, page 14) in a way that was not intended.

The Appeals Committee discussed AbbVie's assertion that a superiority claim should include all outcome measures in the claim and/or qualifier. The Expert Rheumatologist Committee member advised the Appeals Committee that the DAS28 is a community used outcome measure and the target audience would expect that the measure on which this claim is based would be DAS28. With respect to radiographic progression data, any changes on this wide scale would be very small and would not be meaningful. The Appeals Committee agreed unanimously that the target audience for this claim would not be misled by it. The Appeals Committee unanimously agreed that the claim was not in breach of Section 1.1 or 1.3 of the Code.

The Appeals Committee were not convinced by AbbVie's arguments that the claim and qualifier did not meet the requirements of flowchart at Figure 1 of the Code of Conduct Guidelines (version 3). The Appeals Committee firstly noted the statement on the front cover of the Guidelines that advises *"to be read in conjunction with the Code of Conduct Edition 17"* as well as the Disclaimer on page 1 of the Guidelines that advises *"The Edition 17*

Guidelines (version 3) is provided for guidance only and does not cover all code provisions. Pharmaceutical companies should not rely on this document alone. Please refer to Edition 17 of the Code of Conduct for all provisions". On this basis, the Appeals Committee unanimously agreed that reliance solely on Figure 1 to interpret whether the claim was compliant was not appropriate.

Further, the Appeals Committee noted that Section 1.8 of the Code of Conduct states *"…claims must be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter"*. The Appeals Committee unanimously agreed that the claim and qualifier used by Roche met these requirements and was therefore not in breach of the Code of Conduct.

The Appeals Committee unanimously agreed that the claim subject to complaint had met the requirements of the Code of Conduct for comparative claims, and that it had been appropriately qualified. The Appeals Committee noted that in this case the ADACTA study had demonstrated superiority for Actemra on both primary and secondary endpoints. It is the Appeals Committee's opinion that if a superiority study did not achieve its primary outcome measure, a superiority claim based on a secondary outcome measure should not be made.

The Appeals Committee agreed unanimously to uphold the decisions of the Code of Conduct Committee.

Sanction

As the Appeals Committee confirmed the findings of the Code of Conduct Committee, it did not alter the sanctions imposed by that Committee. The Appeals Committee agreed unanimously that as the appeal was not successful, the appeal bond paid by AbbVie would be retained by Medicines Australia.

1104 – Novartis Representative Conduct

Subject Company: Novartis Pharmaceuticals Australia Pty Ltd

Complainant: Biogen Idec Australia Pty Ltd

Product: N/A

Complaint

Biogen Idec alleged that an email communication sent by a Novartis employee to sales representatives of two other pharmaceutical companies that compete in the MS therapeutic area was in breach of the Code of Conduct. Biogen Idec asserted that the email communication demonstrated a lack of ethical conduct and professionalism by the Novartis representative because its content was not accurate and was disparaging. Further, Biogen Idec alleged that the communication was distributed with the intent of creating an unfavourable and inaccurate perception of a medication that is likely to be a commercial threat to the other companies. Biogen Idec further asserted that the email was effectively promoting an unapproved product.

Sections of the Code

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

- Section 1.4 Unapproved Products and Indications

- Section 5.2 Roles and Ethical Conduct
- Section 9.14 Discredit to and Reduction of Confidence in the Industry

Response
Novartis responded that the email communication had been an isolated incident and was not in accordance with Novartis' policies. The email was intended to inform the other company representatives about an article about to be published in the *New England Journal of Medicine.* Novartis confirmed that the email had not been sent to any healthcare professional or members of the general public. Whilst the email was not consistent with company policies, Novartis argued that the conduct was not of sufficient gravity to be unethical or unprofessional. Novartis denied that there had been any intent to influence the views of other sales representatives or to encourage them to discuss the information with healthcare professionals.

Code of Conduct Committee decision
The Committee agreed by unanimous decisions that the activity did not breach Sections 1.4, 5.2, or 9.14 of the Code.

Sanction
As no breach was found, no sanction was imposed by the Committee.

Code Committee consideration of whether the complaint was frivolous or vexatious
A majority of the Code Committee formed the view that this complaint might be regarded as frivolous or vexatious, having regard to the following factors:

(i) there had been considerable communication between the companies during intercompany dialogue, with a number of strategies suggested by Novartis to resolve the complaint;
(ii) Biogen Idec had failed to specify the respects in which the email was claimed to be inaccurate when asked by Novartis to do so;
(iii) the submission of this complaint might have been premature, and continuation of dialogue and acceptance of the actions proposed by Novartis should have resolved the issue;
(iv) following the inter-company dialogue, the lack of substance to the complaint should have been apparent;
(v) the differences between the parties' records of their dialogue might be indicative of vexatious intent.

The Committee therefore requested that Biogen Idec provide a justification as to why this complaint should not be considered frivolous or vexatious and in breach of Section 25 of the Code and as to why the Committee should not impose a fine for abuse of the Code.

Biogen Idec response to allegation of vexatious or frivolous complaint
Biogen Idec stated that the company was very sincere in their efforts to resolve this matter with Novartis, but the significant differences in what is deemed ethical conduct could not be resolved through intercompany dialogue. The complaint was raised with the Code of Conduct Committee to judge objectively what behaviour should or should not be condoned by the industry. In Biogen Idec's view, the Novartis representative's conduct was a serious lapse of ethical behaviour that could bring the industry into

disrepute, which therefore needed to be corrected.

Consideration of the complaint
The Committee considered Biogen Idec's response to the allegation of making a vexatious or frivolous complaint. The Committee noted that its role in this review was not to revisit the original complaint, but to focus solely on the company's response to the Committee's enquiries.

The Committee noted that the complaint was an unusual matter to be presented to it for adjudication. The Committee queried its role in setting precedence in these types of matters. Specifically, it questioned whether communications between two companies falls within the remit of the Code of Conduct. The Committee recommended that this needs to be clarified in the next edition of the Code of Conduct and requested that this matter be raised with the Code Review Panel.

The Committee acknowledged that there had been substantial intercompany dialogue between the companies involved in this matter, and noted that Novartis had made significant concessions during that process. While the Committee agreed it is a company's right to send a complaint to the Code Committee when agreement cannot be reached during intercompany dialogue, this complaint was an example where the compromises and corrective action offered by the subject company should have resolved the issue.

The Committee noted that whilst the complaint to Medicines Australia might have been unnecessary, as the intercompany dialogue should have resolved the issue, members debated whether it was, therefore, vexatious or frivolous. There had been substantial intercompany dialogue, but it was acknowledged that people can become locked into a particular point of view, which the Committee felt had occurred in this case. The Committee also acknowledged that the industry relies on the Code of Conduct and the Code Committee to set ethical standards for the industry. Further, there is no other avenue for companies to resolve matters of ethical conduct such as this, except for a Code complaint.

The Committee agreed that the complaint had been unnecessary because it should have been resolved through the actions that Novartis had proposed. However, the Committee agreed by majority decision that the submission of this complaint to Medicines Australia was not frivolous or vexatious and did not breach Section 25 of Edition 17 of the Code of Conduct.

Sanction
As the Committee found no breach of the Code, it did not impose a sanction.

1107 – LEO Pharma Educational Event

Subject Company: LEO Pharma

Complainant: Monitoring Committee

Product: N/A

Complaint
Following its review of Educational Event Reports and subsequent requests for clarification, the Medicines Australia Monitoring Committee believed that an event held by LEO Pharma may be in breach of the Code, and referred the matter to the Code of Conduct Committee for adjudication.

The Monitoring Committee were concerned with the validity of the event and was not satisfied that there was an educational component to the meeting, although there was evidence that significant hospitality had been provided.

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

- Section 9.1 Relationship with Healthcare Professionals - General Principles
- Section 9.3 Educational Events
- Section 9.4 Company Educational Events held in Australia

Response
LEO Pharma had initially thought that the event in question was an educational event and had reported it as such, however now understands that this is not the case. LEO Pharma acknowledged the initial feedback from the Monitoring Committee and agrees with the Committee that this meeting was not an educational event but rather a business meeting.

Code of Conduct Committee decision
The Committee agreed by unanimous decision that the activity was in not in breach of Sections 9.1, 9.3 and 9.4 of the Code of Conduct

Sanction
As no breach was found, no sanction was imposed by the Committee

Consideration of the complaint
The Committee noted that this complaint concerned an event sponsored by LEO Pharma that the Monitoring Committee had reviewed during its annual educational event reports review. The Committee noted that the Monitoring Committee had sought clarification from LEO Pharma twice as to the nature of this meeting and to substantiate the associated costs.

The Committee noted LEO Pharma's explanation that it had incorrectly reported the activity in the first instance and that it should have been considered a business meeting rather than an educational meeting. The purpose of the meeting was to bring together GPs with a specialised interest in dermatology and a specialist dermatologist to discuss establishing a primary care dermatology society to serve the educational needs of GPs. LEO Pharma conceded that the meeting did not have any educational content; it was a business function, which should therefore not have been reported. The Committee noted that in responding to the requests for clarification from the Monitoring Committee, LEO Pharma had amended the details of this event on each occasion – the meeting had been a dinner (not lunch) and a total of 7 healthcare professionals had attended and 3 Leo Pharma staff . The Committee agreed that the cost of hospitality per head was not lavish at $78.27 per head. However, the Committee did note that a third of the participants at the meeting were LEO Pharma employees.

Regardless of whether the event should have been included in the educational event report or another report, the Committee were disappointed by the disorderly way it was reported, which resulted in amendments to the details of the event on two occasions. The Committee strongly recommended that LEO Pharma should review its policies and

principles for approving, collecting and reporting all educational events.

The Committee agreed by majority decision that there had been no breach of Sections 9.1, 9.3 and 9.4 of the Code. However, one Committee member was of the opinion that there was no obvious rationale as to why a pharmaceutical company needs to be involved in the sponsorship of these types of events.

Sanction
As no breach was found, the Committee did not impose a sanction.

1108 – Xarelto Promotional Material

Subject Company: Bayer Australia Limited

Complainant: Prizer Australia / Bristol-Myers Squibb Australia

Product: Xarelto

Complaint
Pfizer/BMS alleged that the term "simplicity" in a sales aid for Xarelto was false and misleading because it implies that all the complexities of prescribing an anticoagulant have been addressed and that the management of patients taking a new oral anticoagulant is simple. Additionally, Pfizer/BMS alleged that there is no substantiation for the claim that Xarelto is simpler than other new oral anticoagulants. Pfizer/BMS asserted that the oversimplification of anticoagulant prescribing in stroke prevention in patients with atrial fibrillation could have significant consequences and a detrimental effect on patient safety.

Sections of the Code
The promotional claims were alleged to be in breach of the following Sections of Edition 17 of the Code:

- Section 1.3 False or Misleading Claims
- Section 1.6 Unqualified Superlatives

Response
Bayer rejected the assertion that the word "simplicity" was false or misleading and strongly objected to the allegation that the safety of patients has been compromised in any way. Bayer highlighted the three qualifying statements associated with the claim that assist readers to correctly understand the information presented in the claim.

Code of Conduct Committee decision
The Committee agreed by unanimous decision that the claims did not breach of Sections 1.3 and 1.6 of the Code of Conduct.

Sanction
As no breach was found, no sanction was imposed by the Committee.

Consideration of the complaint
The Committee noted that a number of issues had been resolved during intercompany dialogue, with only one claim outstanding. Specifically, complaints concerning the claim of "simplicity" in the statements "Xarelto (rivaroxaban) combines simplicity with effective stroke prevention in non-valvular atrial fibrillation (NVAF)" and "Xarelto: a simplified oral anticoagulant" had not been resolved. The Committee agreed that the complaint turned on the use of the word "simplicity" and the context in which it was used.

The Committee noted that the first statement included two qualifiers:

- One tablet, once daily with food, without the need for routine coagulation monitoring; and
- Xarelto is indicated for the prevention of stroke and systematic embolism in patients with NVAF with ≥ 1 additional risk factor for stroke.

The Committee noted that this claim is referenced to both the Approved Product Information for Xarelto and the study *Patel MR et al, for the ROCKET AF investigators (NEJM 2011) [ROCKET AF]*. Further, the Committee noted that ROCKET AF study was a head-to-head comparison of Xarelto to Wafarin.

The Committee noted that there are three novel anticoagulant products in this therapeutic class that have a similar mode of action. The novel oral anticoagulants do not require INR monitoring as a routine aspect of treatment, whereas Warfarin does require regular blood tests and monitoring. The Committee noted that each of these new agents are slightly different in their mode of action, with Xarelto being the only one which is taken once daily with food.

The Committee agreed the use of the word “simplicity” in the claim would be interpreted by clinicians as a comparison with Warfarin and not the other new oral anticoagulants. The Committee agreed that the management of anticoagulation in order to try to prevent stroke is not simple. The Committee acknowledged that a once daily oral tablet without the need for regular blood tests is simpler for patients, but no clinician would be misled to think that prescribing and managing anticoagulant treatment was simple.

The Committee unanimously agreed that the claim did not breach Sections 1.3 and 1.6 of the Code of Conduct as it was not false or misleading, and was appropriately qualified.

The Committee considered that the matters agreed during intercompany dialogue should have resolved the matter without the need for the complaint to have been sent to Medicines Australia.

Sanction
As the Committee did not find a breach of the Code of Conduct, no sanctions were imposed.