Medicines Australia Code of Conduct Quarterly Report January - March 2017

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 January and March 2017. Complaints finalised during this period were in relation to materials or activities conducted under Edition 18 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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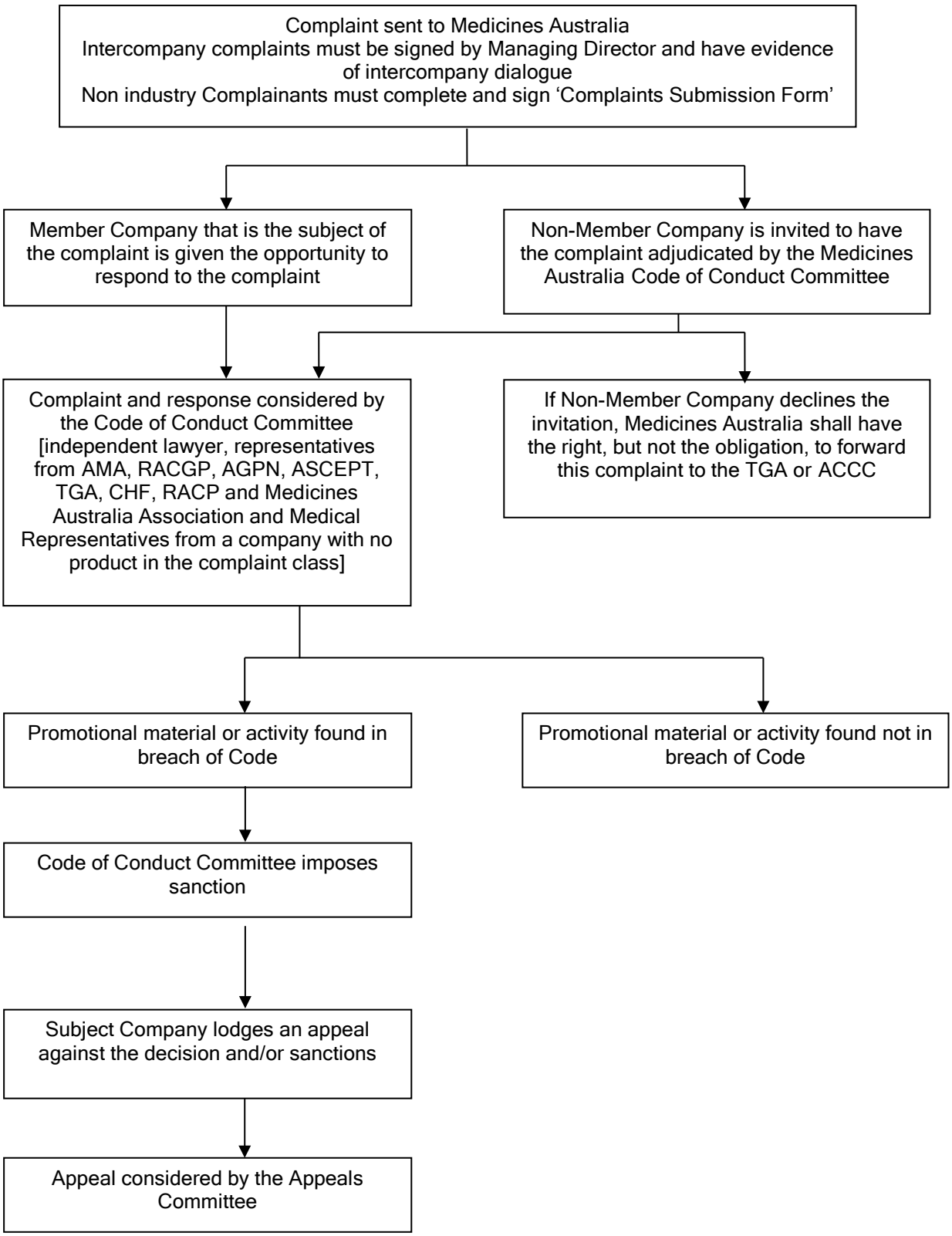
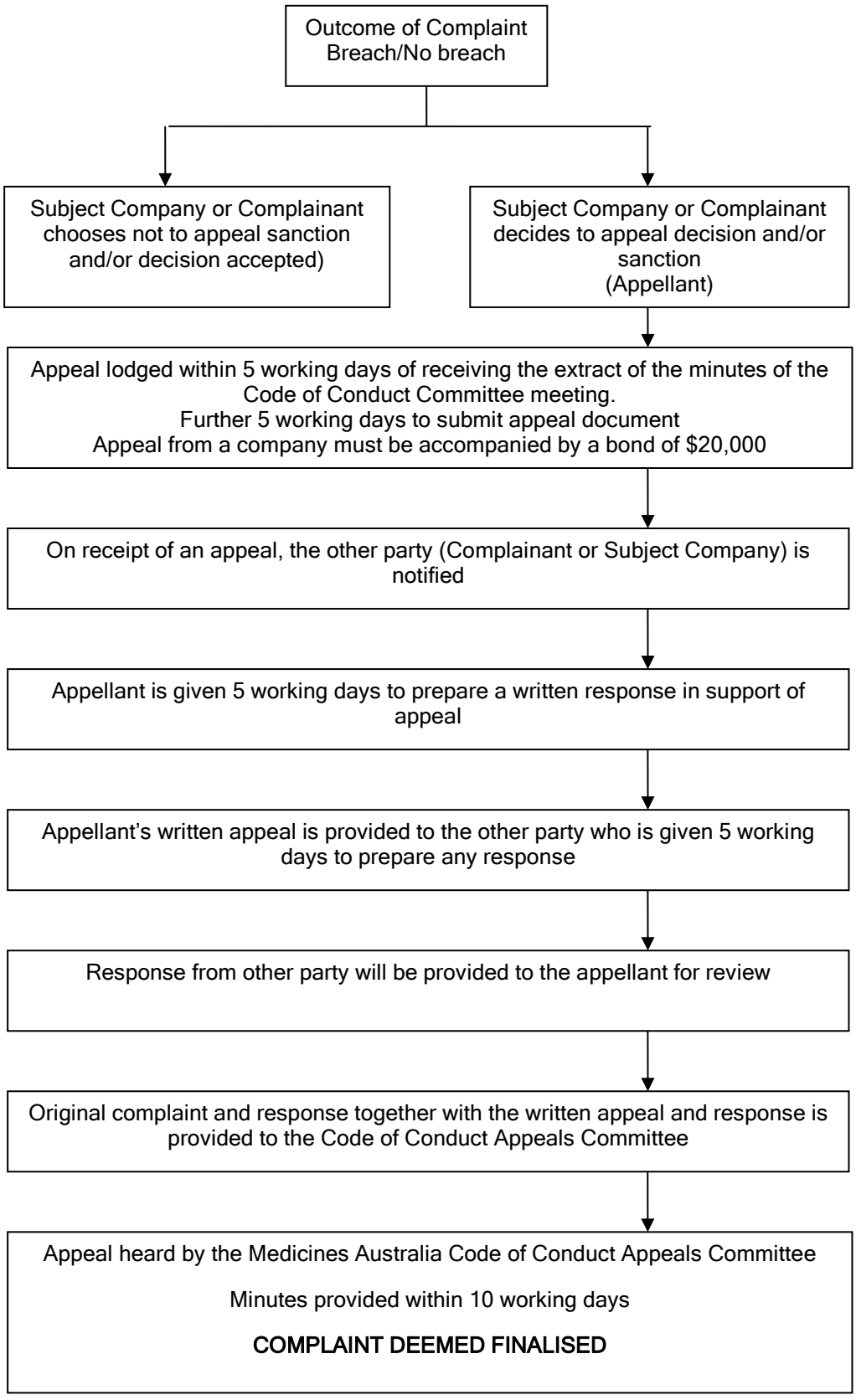
Medicines Australia Code of Conduct Complaints Handling Process



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 January – March 2017

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1139	Amgen Australia	Dosing Guide	Prolia	Healthcare Professional	No breach	N/A
1140	Sanofi Genzyme	Promotional Material	Aubagio	Biogen Australia	No breach	N/A

1139 – Prolia Dosing Guide

Subject Company: Amgen Australia Pty Ltd

Complainant: Healthcare Professional

Product: Prolia

Complaint
The healthcare professional complainant alleged that claims for relative risk reduction of fractures was misleading and in breach of the Code. The healthcare professional complainant particularly argued that the absolute risk reduction for hip fractures with Prolia was 0.5 (placebo effect of 0.7 and drug effect of 1.2). The complainant alleged that expressing this as a Relative Risk Reduction of 40% is misleading. The complainant considered that it is similarly misleading to express the reduction in non-vertebral fractures and new vertebral fractures as Relative Risk Reductions.

Sections of the Code
The claims were alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.3 False or Misleading Claims

Response
Amgen rejected the allegation that the claims for Prolia were misleading or in breach of the Code of Conduct. Amgen asserted that the use of Relative Risk Reduction (RRR) is an appropriate, well-accepted and readily understood way in which to describe the differences in observed fracture rates. Further Amgen noted that RRR is the key parameter used in the clinical study published in the *New England Journal of Medicine* which described the effect of denosumab in reducing fracture risk at key skeletal sites. Further, RRR is included in the Prolia Product Information.

Amgen further argued that a RRR of 40% in hip fractures is very meaningful for patients. RRR is a well-accepted parameter and is used in many promotional materials for healthcare professionals.

Code of Conduct Committee decision
The Committee unanimously determined that the Prolia Dosing Guide was not in breach of Section 1.3 of the Code of Conduct.

Sanction
As no breach was found, no sanction was imposed.

Consideration of the complaint
The Committee discussed the use of Relative Risk Reduction (RRR) in the dosing guide, which was used to demonstrate fracture reduction in patients using Prolia. The Committee also discussed the complainant's allegation that the use of RRR to describe reduction in risk of fractures was misleading and that the use of Absolute Risk Reduction (ARR) would be a more appropriate descriptor of the treatment effect.

The Committee noted that RRR historically has been misused, in many fields including medicine, to exaggerate the effects of an intervention and that it could be misleading if not used in a balanced manner, for example stating a RRR that might be significant statistically but is not clinically relevant because the effect size is relatively small. The Committee also noted that the audience for a communication using RRR is also an important factor, as the general public may not understand how to interpret RRR.

The Committee agreed, however, that the use of RRR in the Prolia Dosing Guide was appropriate and the effect on reducing fracture risk was clinically relevant. The Committee also agreed that RRR would be a familiar concept to the target audience for the Dosing Guide, general practitioners and endocrinologists, who would understand the difference between RRR and ARR. The percentage risk reductions stated in the Dosing Guide were clearly identified as RRR, with the statistical significance (p-value) stated in each case. The Committee further noted that the use of RRR in the Prolia Dosing Guide was supported by the Cummings et al study (the FREEDOM trial) published in the *New England Journal of Medicine*, which reported the RRR. The Committee agreed that the FREEDOM study showed long term data of three years. The Committee further noted that RRR was stated as the main descriptor of Prolia's effect compared with placebo in the Product Information, with ARR also stated in bracketed text.

While the Committee agreed that the use of RRR in this instance was appropriate, it was also of the opinion that it would be best practice to also include ARR data where possible. It is widely accepted that ARR is the clearest way of presenting research results to assist in healthcare professional decision-making. The Committee noted that the Code does not require the use of ARR data in

promotional materials; however the Committee encouraged its use where it is possible and appropriate. In this instance, the Committee noted that the ARR had been included in Tables 1 and 2 in the Approved Product Information and considered that it would be possible for this tabulated information to be communicated in a clear and meaningful manner on a promotional item. However, the Committee did not agree with the complainant that the use of RRR was misleading in the Prolia Dosing Guide.

The Committee agreed by unanimous decision that the Prolia Dosing Guide was not in breach of Section 1.3 of the Code.

Sanction
As no breach was found, no sanction was imposed.

Appeal
The healthcare professional disagreed with the findings of the Code of Conduct Committee and asserted that the use of risk ratios commonly exaggerates both the benefits and harms of products. Further, the Complainant contended that a relative risk ratio does not measure 'risk' as it does not include a risk dimension, such as *"observed deaths per 1000 people"* or similar measure.

The Complainant appealed the decision noting that they believed that the framing of the benefit in relative rather than absolute terms was an attempt to alter the prescriber's perception of the product and therefore is false and misleading.

Appeal Response
Amgen reasserted its position that the use of RRR is a clinically appropriate parameter that is well-accepted and readily understood by the target audience. Amgen also noted that in its decision the Code Committee had stated that the use of RRR in this piece was appropriate.

Appeals Committee decision
The Appeals Committee was not persuaded that the decision of the Code of Conduct Committee (Code Committee) in relation to this complaint involved any error that required the decision to be altered or set aside. The decision of the Code Committee was confirmed. The Appeals Committee agreed by unanimous decision to not uphold the appeal.

Sanction
In confirming the decision of the Code Committee, the Appeals Committee also confirmed the Code Committee's decision to not impose any sanction.

Consideration of the Appeal
Prior to consideration of the appeal, the Chairman called for the declaration of any conflicts of interest. No conflicts of interest were declared and the meeting proceeded.

The Chairman explained the process for consideration of an appeal. 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 Committee should be set aside or varied.

The Chairman invited the Complainant to give their appeal presentation. The following summarises that presentation and discussion with the Appeals Committee.

The Complainant summarised their background, noting that as a general practitioner they were familiar with being visited by pharmaceutical industry sales representatives on a regular basis. During a visit from an Amgen representative, the Complainant received the promotional item for Prolia that they considered was very misleading. The Complainant's concern centred on the use of RRR rather than Absolute Risk Reduction (ARR).

It was the Complainant's opinion that health statistics are generally poorly understood by general practitioners and, in particular, that the difference between RRR and ARR is not well understood even by a learned healthcare professional.

The use of RRR had been associated with three statements in the Prolia promotional item:

- New vertebral fractures: ↓ 68% RRR ($p<0.001$)
- Hip fractures: ↓ 40% RRR ($p<0.04$)
- Non-vertebral fractures: ↓ 20% RRR ($p<0.01$)

The Complainant stated the key issue with using RRR is that it fails to discriminate between large treatment effects and very small treatment effects in terms of absolute numbers. The Complainant asserted that by using RRR expressed as a percentage without knowing other parameters, the information was very difficult to interpret. When reviewing the piece, the Complainant could not determine easily what the percentage risk reductions related to. It was contended that without

additional information, which would need to be obtained from the Product Information or clinical study, a reader would not be able to properly interpret the potential benefit of the product. Simply stating the RRR percentage, which gives the impression that there is a large reduction in risk because the number is large (i.e. 68%), is misleading without further information that would give a better understanding of efficacy.

The Chairman sought an understanding from the Complainant, as a trained healthcare professional and the intended audience of the piece, whether their individual knowledge and training gave them the ability to understand and interpret the promotional piece. The Complainant responded that unless the parameters around the numbers are provided in the piece, it is impossible to interpret the figures without reviewing the Approved Product Information or reading the supporting paper in detail. It was the Complainant's opinion that a busy general practitioner would not be able to calculate the absolute risk reduction from the RRR without additional information provided in an easily accessible manner, such as in the piece itself.

In their presentation, the Complainant presented data from the referenced study and data from another study in a different osteoporosis treatment. This was to illustrate that without the inclusion of additional information, Prolia may appear to be superior because the percentage RRR number is larger, whereas the higher ARR of the other product indicated that it might provide greater benefit to patients although its percentage RRR number is smaller. This demonstration, the Complainant asserted, showed that the use of a RRR without additional information is misleading to a reader. The use of ARR or Number Needed to Treat (NNT), for example, would greatly reduce the risk of healthcare professionals being misled.

An Appeals Committee Member strongly agreed with the complainant that ARR should be included in promotional materials provided to doctors.

Another Committee Member disagreed with the statement that healthcare professionals are statistically illiterate, and asserted that many would be able to understand the difference between RRR and ARR. This Committee Member queried whether it was the lack of information in the piece, or the inability of the Amgen sales representative to adequately explain the statistic that was more of concern to the complainant. The Complainant explained that they believe that all the information should be contained within the piece, and that a company representative should not be relied upon to explain the data to healthcare professionals. The quality of the information provided should be enhanced to ensure that value is derived from doctors' interactions with company representatives. So long as the necessary information is provided, a general practitioner should be able to interpret the data. However, the Complainant contested that if they are expected to read every paper and complete complex calculations to derive the data needed to make an informed decision, most busy general practitioners would not do so and would rely solely on the data provided in the promotional piece.

The Chairman thanked the Complainant for their presentation, and invited Amgen to make their presentation. The following summarises that presentation and discussion with the Appeals Committee.

Amgen maintained that the promotional material was not misleading. The aim of the piece was the Quality Use of Medicines, reminding healthcare professionals of the 6 month dosing regimen for Prolia and the need for patients to also receive calcium and vitamin D supplements. The Dosing Guide was for GPs and some specialists and was not to be given or shown to patients. Amgen confirmed that it took matters of compliance seriously and submit to Medicines Australia's Code of Conduct, which is supported by a strong compliance culture in the organisation.

Amgen then invited an independent expert in management of osteoporosis to make a presentation to the Appeals Committee. This expert is a professor with a long-standing interest in the field of osteoporosis and the presentation was to assist the Appeals Committee in understanding and interpreting the knowledge base in this therapeutic area. The Professor had declined any payment from Amgen for their involvement in this matter.

The Professor provided an overview to the Appeals Committee as to the difference between RRR and ARR. In this overview, the Professor noted that:

- Relative Risk Reduction is how much a risk is reduced in the treated population when compared to the control (or placebo) population.

- Without knowing the untreated risk, the effect size of treatment cannot be assessed
- A treatment with a very large relative risk reduction will have a small absolute benefit in low risk individuals
- Modest relative risk reductions can have major clinical importance if there is a high underlying risk
- Absolute risk reduction is the absolute difference in outcomes between the treated population when compared with the control (or placebo) population
- ARR makes no explicit comparison to the untreated population but depends upon underlying risk

It was the Professor's opinion that ARR is less intuitive to interpret than RRR. In order to make a comparison, the Professor argued that a reader needs to know the underlying risk to make the comparison meaningful. Further, the use of NNT data would not be helpful unless a reader also knows the ARR in the first instance.

The Professor noted that the Complainant's arguments based on a comparison between the ARR and RRR for Prolia and another unnamed product in this therapeutic class were flawed. The studies that the data were derived from cannot be compared because they were studies of different patient populations, who had different baseline risk of fracture, with different study parameters and therefore the data is not comparing the same endpoints, resulting in meaningless information. Further, the Professor noted that in osteoporosis, there have been no head to head studies conducted. This is not due to lack of willingness by companies, but due to the requirement of international regulators such as the US FDA for studies of osteoporosis treatments to be placebo-controlled.

The Professor noted that use of ARR may seem appealing, however it cannot be meaningfully applied to an individual patient unless their individual absolute risk is estimated. That is, unless the treating physician understands the extent to which an individual patient matches the population in a study, the use of ARR is not helpful to a physician. The Professor noted that RRR is stable over a range of underlying absolute risk levels and is intuitively understood. Further, the Professor noted that due to the expansion of treatment options in osteoporosis, more people were being treated – resulting in a shrinking control population. This is resulting in a reduction of absolute risk in patients being enrolled in clinical trials.

The Amgen representatives then addressed the Appeals Committee and restated that they rejected the assertion that by omitting the ARR or NNT that Amgen had breached Section 1.3 of the Code. Amgen firmly believed that the Prolia piece was fair, balanced, and was not misleading. They, too, contested the allegation that healthcare professionals were statistically illiterate.

Amgen asserted that it had used RRR as it was meaningful and relevant to physicians, and well understood by the target audience. As explained by the Professor, RRR is readily applicable to the clinical environment and supports informed decision making. In the absence of knowing an individual patient's risk, the RRR is a clearer and more interpretable than ARR.

Amgen further rejected the assertion that the figure of 68% RRR for new vertebral fractures was grossly misleading, as asserted by the Complainant, as this was the primary end point of the study used to support the claim. The study was adequately powered to detect a statistical difference. The Cummings et al study (2009) was in low risk patients and showed that the treatment effect for hip fracture was a 0.5% reduction (0.7% cumulative incidence of hip fracture in the treatment group vs 1.2% cumulative incidence in the placebo group), which represented a relative decrease of 40%. Amgen argued that a relative risk reduction was an important effect of treatment. Finally, given the financial impact of hip fractures in Australia of approximately $700m per annum in direct and indirect costs, the relative risk reduction represents a significant potential cost saving.

Amgen concluded its presentation by restating that they contest the assertion that the Prolia Dosing Guide was in breach of Section 1.3 of the Code through the use of RRR alone. Amgen noted that the Code does not specify the use of RRR, ARR or NNT and that Amgen believe the use of RRR to be appropriate in this promotional material.

Amgen highlighted to the Appeals Committee that the Code Committee's decision was unanimous, and this was reflected in the Committee's reasons for decision which stated that the use of RRR in this piece was appropriate. Amgen stated that no evidence had been provided by the Complainant to

show that the Code Committee's decision had been in error.

The Chairman then queried Amgen regarding the Complainant's assertion that the company representative had not been able to provide more clarity about AAR during their visit in 2016. Amgen noted that this allegation was not made in the original complaint, nor the subsequent appeal submission and therefore Amgen had not had the opportunity to conduct an internal investigation on the matter.

The Chairman then invited the Complainant to respond to the information provided in Amgen's presentation and to provide their closing comments. The Complainant took the opportunity to restate that they believed most healthcare professionals do not understand statistical concepts such as RRR and ARR. The Complainant considered that the promotional piece was designed to show a large number to GPs, which was misleading. The Complainant remained firmly of the opinion that the promotional material should have included ARR and NNT or a simple statement communicating this information in order to assist in the understanding of the information provided. The Healthcare Professional concluded by stating that they believed the Code Committee fell into error by overestimating the ability of the average general practitioner to interpret the information presented in the way that it was. Relying on a doctor to read the Product Information and read the clinical evidence in order to correctly interpret the promotional material is misleading.

The Chairman thanked both the Complainant and Amgen for their presentations and excused them from the meeting.

The Appeals Committee considered that it was unusual for ARR or NNT figures to be stated in promotional materials, in part because these data might not be always provided in referenced studies.

The Appeals Committee acknowledged that communication of risk reduction is a contentious area and noted that the use of RRR over ARR has been debated at length. The Appeals Committee noted that significant effort is spent in educating healthcare professionals during their training about clinical statistics and, indeed, newer graduates often have better skills in this area due to this greater focus in their training.

The Appeals Committee determined that it could not find that Amgen had breached the Code of Conduct as the Code does not at present require the inclusion of ARR or any other risk parameter in promotional materials. The Appeals Committee agreed with the Code Committee that RRR is a widely used way of communicating risk reduction and that the evidence used to support the RRR claims in the Prolia Dosing Guide was appropriate. The Appeals Committee noted that just providing the ARR could also mislead a GP, because a prescriber must also consider the risk of an individual patient and how they compare to the relevant study population. The Appeals Committee unanimously agreed to confirm the Code Committee's decision to find no breach of Section 1.3 of the Code. The appeal was not upheld.

The Appeals Committee recommended, however, that Medicines Australia should provide further guidance on the use of clinical statistics by pharmaceutical companies in promotional and other materials. Specifically, the Appeals Committee considered that the inclusion of additional parameters and presenting information in a clear way would enhance the quality use of medicines and would assist a healthcare professional to make an informed decision about prescribing a medicine. The Appeals Committee recommended that any future iteration of the Code of Conduct should incorporate additional guidance on the communication of risk using statistics such as ARR, RRR and NNT.

1140 – Aubagio Promotional Meterials

Subject Company: Sanofi Genzyme

Complainant: Biogen Australia

Product: Aubagio

Complaint
Biogen asserted that images used by Sanofi Genzyme in material promoting Aubagio, which depicted a female holding a finger to her lips, constituted graphical representations and promotional claims that conveyed positive attributes of the product. The imagery appeared on a number of items: banners displayed at healthcare professional conferences, an information guide distributed at those conferences, and a patient support

program leaflet for patients. Biogen asserted that the images were to represent that the patient's experience on the product will be a quiet, calm and uneventful one. Biogen further asserted that the images downplayed serious side effects of the product or conveyed that side effects were minimal. Biogen argued that some side effects of the product could be fatal, and require regular monitoring.

Biogen argued that the images were in breach of the Code because they were not accurate, balanced, did not make a responsible claim and were misleading by implying that the product is without serious side effects. Further, Biogen asserted that the images should be considered promotional claims, and therefore should not appear on materials intended for patients, such as the patient support program leaflet.

Sections of the Code
The claims were alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 13.7 Materials for Use with Patients (Patient Aids)
- 17 Patient Support Programs

Response
Noting that the images were not accompanied by any written claims, Sanofi Genzyme rejected the allegations that the images in the Aubagio materials constituted a promotional claim with reference to Section 1.1 of the Code, which refers to "any statement … whether verbal or written". Sanofi Genzyme denied that the imagery on its own conveyed a promotional claim in relation to efficacy or safety. Sanofi Genzyme asserted that the material in which the imagery appeared contained valuable and balanced information for clinicians and patients who have been prescribed Aubagio. In rejecting the allegation that the images are promotional claims, Sanofi Genzyme also rejected the assertion that the images should not be used in materials intended for patients.

In their response, Sanofi Genzyme asserted that the complaint submitted by Biogen was vexatious and frivolous and alleged that Biogen was therefore in breach of Section 27, Abuse of the Code.

Code of Conduct Committee decision
The Committee unanimously determined that the Aubagio Promotional Material was not in breach of Section 1.1, 1.3, 13.7 or 17 of the Code of Conduct.

The Committee agreed unanimously that the action taken by Biogen in submitting the complaint to Medicines Australia was not frivolous or vexatious.

Consideration of the complaint
The Chairman opened the meeting with a summary of the complaint presented to the Committee for its adjudication. The Chairman explained that there were originally two parts to the complaint, which were described in the complaint submission as Complaint A and Complaint B. He noted that subsequent to the submission of the complaint, and after intercompany dialogue, Complaint B had been withdrawn by the complainant and therefore did not require consideration by the Committee.

The Chairman noted that Complaint A related to the use of two images, both of which were described by Biogen in its complaint as a "*female making a 'shh' gesture*". These images are of two different women in two different depictions. The first is a close-up headshot of a woman, which was cropped to focus only on the lower portion of her face. In this image, the woman is smiling with closed lips and holding the index finger of her right hand to her lips. This image will be identified as Image 1 in this statement of the reasons for decision. The second image is of a woman aged approximately in her twenties, appearing in a social setting with three other individuals. The image is captured in a documentary style, with the other individuals in the image facing away from the camera, while the woman is facing the camera. As in the other image, the woman is smiling with her lips closed while holding the index finger of her left hand to her lips. This image will be identified as Image 2 in this statement of the reasons for decision.

Image 1 appeared on:

- two banners displayed at educational events for healthcare professionals
- an Information Guide for patients
- a Patient Support Program leaflet for patients

Image 2 appeared only in the Information Guide for patients.

The Chairman noted that Biogen had alleged that these images were making promotional claims about the product, Aubagio. Specifically, it was alleged that the images

conveyed that a patient using the product will have an experience that is 'quiet' and 'uneventful', which had minimised the potentially serious side effects of the product. The Chairman noted that there is no allegation of lack of substantiation as to the effectiveness of the product; the complaint related primarily to the images being promotional and to possible claims about side effects.

The Chairman reminded the Committee that some of the material had been subject to a previous complaint (1138 – Aubagio and Lemtrada Advertisements; September 2016) considered by the Committee. Those materials utilised Image 1, but in that case the image was accompanied by certain claims in written form. One of the claims ("quietly") had been found, in association with Image 1, to be in breach of the Code of Conduct as being false and misleading and unable to be substantiated. The Chairman noted that in complaint 1138, the image had been mentioned, but only in conjunction with the claims and not as a separate alleged breach of the Code. In finding a breach for one claim in complaint 1138, the Code Committee had required that Sanofi Genzyme withdraw the claim found in breach and to not use the claim again in the same or similar form in any future materials. The Chairman noted that, because of the form that complaint had taken, the sanctions imposed by the Committee had related to cessation of the use of a claim conveyed by the word "quietly", and had not referred expressly to the imagery that accompanied it.

The Chairman then recommended that the Committee consider a number of fundamental questions in its adjudication of this complaint:

1) whether the images could be regarded as conveying any representations;
2) if so, what the images conveyed in each context raised in the complaint;
3) whether the material for healthcare professionals breached the Code in the ways alleged; and
4) whether the material for consumers breached the Code in the ways alleged.

In considering these questions, the Committee determined that it appeared likely that an image on its own, even without any captions or written claims, could in some contexts convey representations that promoted a product, and that whether this was so would depend on both the image and the full context in which it appeared. The Committee noted that there are often widely different interpretations that may be taken from an image if it appears by itself.

As to the two images subject to complaint, the Committee agreed that the either image could be regarded as depicting a 'shh' gesture as alleged by Biogen in the complaint. However, the Committee also agreed that other interpretations relating to keeping a secret or the number one could be taken from the images. The Committee did not find that any interpretation relating to the side effects of Aubagio could reasonably be drawn from either image. The Committee agreed unanimously that the images were ambiguous in their meaning and did not convey anything specific about the product. In particular, a majority of the Committee was satisfied that no reasonable view of the images conveyed anything about side effects.

A minority of the Committee suggested that use of Image 1, even by itself, at approximately the same time as the distribution of the Aubagio materials subject to complaint 1138 might act as a reminder of the "quietly" claim in that material, and would therefore contribute to healthcare professionals recalling that claim. However, a majority of the Committee did not agree with this proposition.

The Committee specifically considered the use of the images within the materials intended for patients. The Committee did not consider that the inclusion of the images was making promotional claims about the product to patients. Rather, the Committee considered that the inclusion of the images was more likely to be, simply, to make the materials more visually appealing to patients or to make patients more comfortable with the materials they were reading. The Committee found that the materials were not in breach of Sections13.7 or 17 of the Code.

The Committee agreed by unanimous decisions that image 1 and image 2 did not make promotional claims for Aubagio and therefore were not in breach of Sections 1.1, 1.3, 13.7 and 17 of the Code of Conduct.

The Committee then turned to consider Sanofi Genzyme's allegation that the submission of this complaint was frivolous or vexatious. The Committee considered that overall the complaint was difficult to navigate and somewhat disorganised. The Committee felt this was underscored by the fact that intercompany dialogue did not appear to have

been concluded before the complaint was submitted, noting that a substantial part of the complaint had been resolved between the companies only after the complaint had been submitted to Medicines Australia. Further, the Committee noted that Biogen had made an erroneous statement in its complaint, in alleging that the Aubagio Product Information states that the product has *"serious adverse effects (AEs) such as hepatotoxicity and peripheral neuropathy, and has resulted in patient fatality…"*. The Committee agreed with Sanofi Genzyme that this was a misrepresentation of the data contained in the Product Information.

However, the Committee also noted that this complaint related to an image that had appeared in promotional material previously the subject of complaint 1138, as well as a second, similar image, and that these circumstances gave a reasonable basis to the argument made by the complainant. The Committee acknowledged that it was Biogen's right to make the complaint in the manner in which it did. However, the Committee recommended that Biogen should in future focus on ensuring that a complaint had been fully explored through intercompany dialogue prior to submitting it.

The Committee agreed unanimously that the complaint was not frivolous or vexatious.

Sanction
As no breach was found, no sanction was imposed.