Medicines Australia Code of Conduct Quarterly Report January - March 2012

Medicines Australia Code of Conduct

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 16 (Effective 1 January 2010).

This report covers all complaints finalised between January-March 2012. Complaints finalised during this period were in relation to materials or activities conducted under Edition 16 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/

How to contact Medicines Australia

Address:
Level 1, 16 Napier Close
DEAKIN ACT 2600

Phone: 02 6122 8500

Fax: 02 6122 8555

Email: secretarycodecommittee@medicinesaustralia.com.au

How do I obtain a copy of the Code?

Copies of Edition 16 of the Code (effective from 1 January 2010) are available from Medicines Australia. An order form is available from http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-currentedition/

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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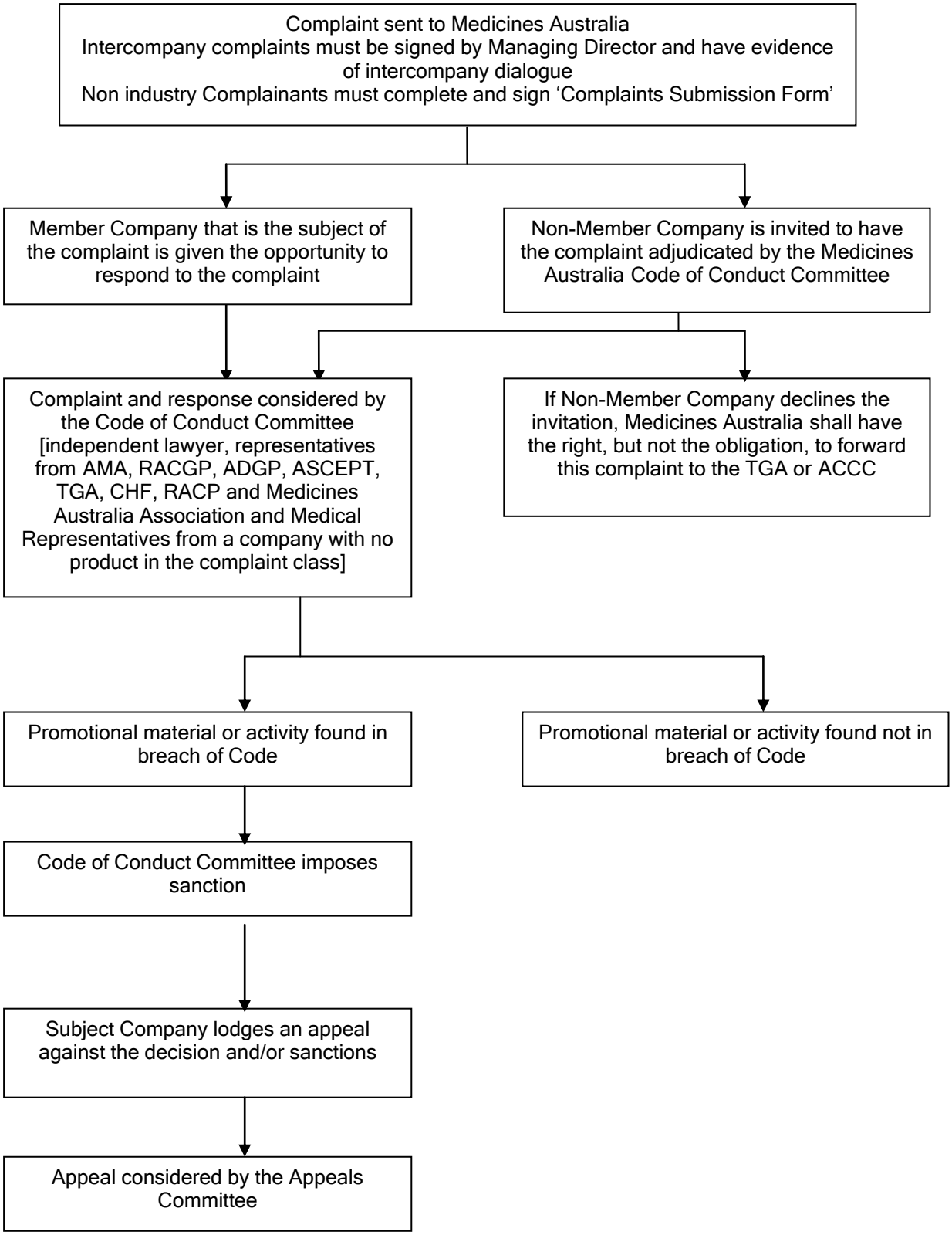
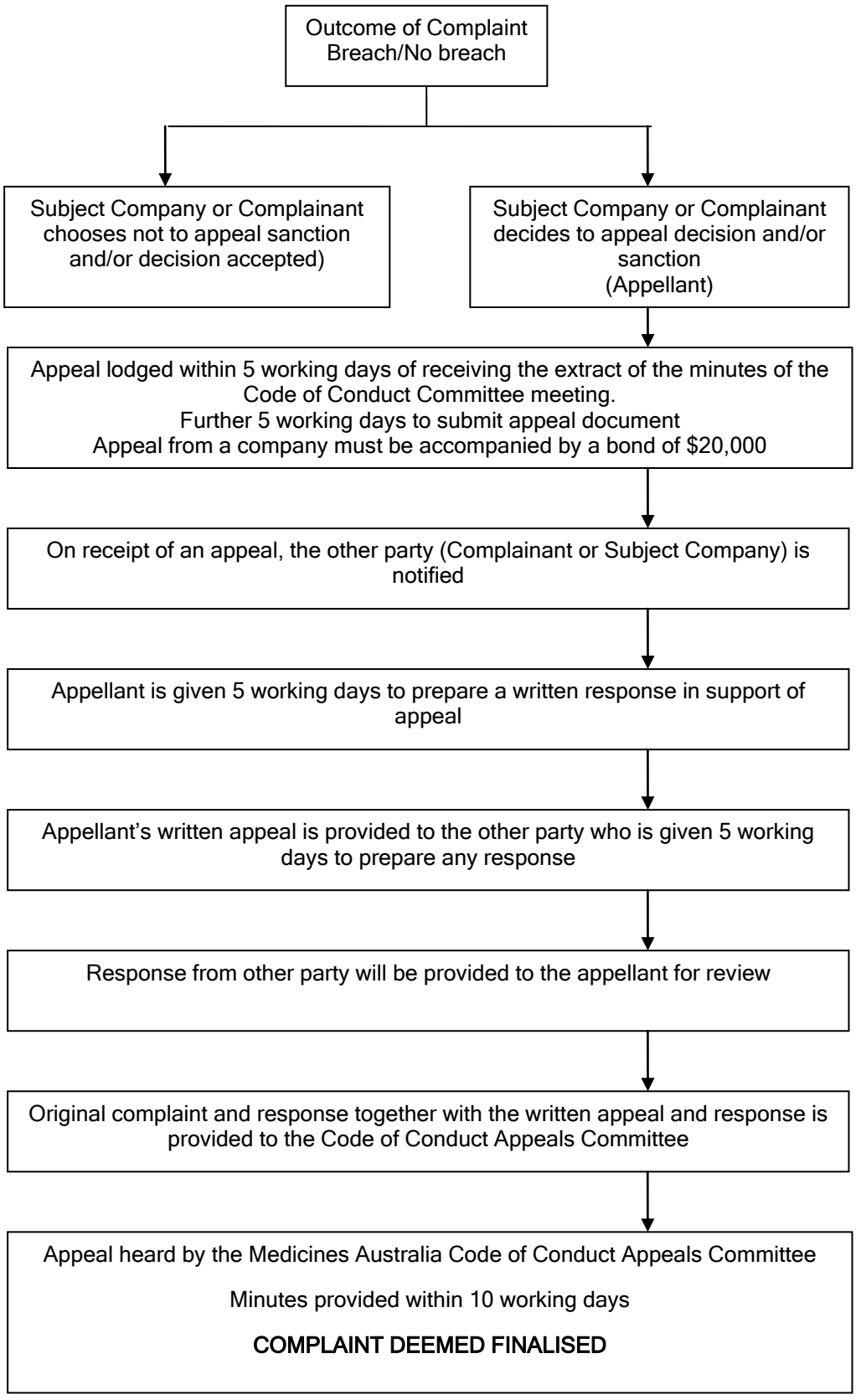
Medicines Australia Code of Conduct Complaints Handling Process



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 six 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 six 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.

Fines (applicable under Edition 15 of the Code)

Breach	Fine
Technical breach Minor breach Moderate Severe breach	Maximum of $100,000
Severe breach where activities have ceased Breach repetitions Repeat of previous breach	Maximum of $200,000

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 $300,000

Guidelines for determining Code sanctions can be found at page 114 of the Code of Conduct Guidelines (for Edition 16) on the Medicines Australia website at http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/

Table of finalised complaints January – March 2012

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1077	sanofi-aventis	Media segment	Actonel EC	Healthcare professional	• Breaches of Sections 12.3 and 12.4 • No breach of Section 9.13	$40,000
1079	Boehringer Ingelheim	Website	Pradaxa	NSW Therapeutic Advisory Group (NSW TAG)	• Breaches of Sections 12.3, 12.8 and 12.9	$125,000
1080	Lundbeck	Leave Behind	Lexapro	Healthcare Professional	• No breach of Section 1.3	N/A

Actonel EC Media Segment – 1077

Subject Company: Sanofi

Complainant: Healthcare professional

Product: Actonel EC

Complaint
The complainant alleged that an interview aired on Perth radio station 6PR breached the Code of Conduct as it had advertised Actonel EC to the general public. The interview with a healthcare professional was conducted by announcer Howard Sattler on 14 June 2011. The complainant questioned Sanofi's involvement in setting up the interview and the relationship between Sanofi and the healthcare professional interviewed.

Sections of the Code
The Secretariat had asked Sanofi to respond to the complaint with regard to the following Sections of Edition 16 of the Code:

- 9.1 General principles for relationships with healthcare professionals
- 9.12 Gifts and offers
- 9.13 Discredit to and reduction of confidence in industry
- 12.3 Promotion to the general public
- 12.4 Product specific media releases
- 12.5 General media articles
- 12.7.1 Disease education activities in any media

Response
Sanofi acknowledged that the interview was a result of the release of a product specific media release regarding Actonel EC. Sanofi contended that the media statement was compliant with the Code of Conduct. The interview was with a healthcare professional spokesperson that had been identified by Sanofi because he is an expert in osteoporosis. Sanofi stated that there was no financial or material agreement between Sanofi for the healthcare professional to participate in the media interview. Sanofi also stated that no financial payment or arrangement was in place with 6PR.

Sanofi considered that the media statement was compliant with the Code. Sanofi argued that it could not be held responsible for the questioning style of the interviewer and had no control over the questions he asked of the expert spokesperson beyond the information that was contained in the media release. Sanofi considered that the statements made by the expert spokesperson during the interview were educative and informative. Sanofi stated that it had not breached any section of the Code.

Code Committee decision
By unanimous decisions, the Committee found no breach of sections 9.1, 9.12, 12.5 and 12.7.1 of the Code of Conduct. Additionally, the Committee found by majority decisions no breach of sections 9.13, 12.3 and 12.4 of the Code of Conduct.

Consideration of the complaint
The Code Committee listened to the recorded radio interview prior to commencing its consideration of the complaint.

The Code Committee noted that complaint had initially been lodged by the healthcare professional with the Therapeutic Goods Administration (TGA), which had referred the complaint to Medicines Australia. The Code Committee further noted the

email correspondence between the Medicines Australia Secretariat and the complainant. The Secretariat had sourced the recorded interview subject to complaint and provided it to the complainant. The complainant had not taken up the offer of an independent facilitator to assist in formulating their complaint. The Secretariat had identified a broad scope of potentially relevant sections of the Code against which to assess the complaint based on the complainant's correspondence. The Code Committee questioned the applicability of some sections of the Code to the complaint.

The Code Committee discussed the individual sections of the Code to which Sanofi had been requested to respond. In relation to Sections 9.1 and 9.12, the Code Committee noted that Sanofi had stated that there was no financial relationship between the company and the healthcare professional interviewed or between the company and the radio station. The Code Committee also noted that Sanofi had advised in its response that the communications agency had provided the healthcare professional with a gift of a bottle of wine and chocolates following the interview as a thank you gift. Sanofi had advised that this was against its internal company protocols as well as the Code of Conduct and had taken corrective action with the communications company. The Code Committee agreed that this was not consistent with the Code; however it was inadvertent and had been addressed. The Code Committee agreed that as the gift was provided after the event, it could not be construed as influencing the healthcare professional's conduct during the interview in any way. The Code Committee cautioned Sanofi to ensure that its revised protocols ensured this did not reoccur. In a unanimous decision no breach of Sections 9.1 or 9.12 of the Code was found

The Code Committee reviewed the media statement issued by Sanofi on 14 June 2011 which Sanofi had acknowledged resulted in the radio interview. The Code Committee considered that the media statement to the lay media complied with the requirements as set out in Section 12.4 of the Code of Conduct. The media statement was released to announce the PBS listing of Actonel EC, which was permitted by the Code, and was determined to be a balanced statement that included the required information regarding product precautions, adverse reactions, warnings, contraindications and interactions and had included the minimum product information and a URL for the consumer medicine information.

The Code Committee examined the evidence supplied by Sanofi which showed that the media statement had been provided to radio station 6PR by Sanofi's communications agency. This statement was accompanied by information about the health professional that had been identified in the media statement by Sanofi as a potential expert spokesperson. The information provided by the communications agency to 6PR met the requirements of Section 12.4 of the Code of Conduct. One member of the Code Committee was concerned that although the media statement and accompanying materials were consistent with what is permitted under the Code, the end result was a radio segment that encouraged members of the general public to seek a prescription for a specific prescription only medicine. In a majority decision the Code Committee found no breach of Section 12.4 of the Code.

The Code Committee discussed the content of the radio interview. The Code Committee understood that the interviewer is a well-known talk-back radio host Howard Sattler on Perth radio. The Code Committee agreed that the healthcare professional interviewed is unlikely to have been provided with advance notice of the questions that Mr Sattler would ask. The Code Committee also agreed that neither Sanofi nor its communications agency would have received advance notice of the interview questions. The Code Committee agreed that neither Sanofi nor its communications agency could have had any influence on the interview style or content and they could not be held responsible for the line of questioning chosen by the interviewer.

The Code Committee discussed the statements and responses by the healthcare professional interviewed. One Code Committee member who has had experience being interviewed for programs similar to the one subject to this complaint noted that the tactics of an interviewer are designed to take the interviewee down a particular path. If someone is not particularly experienced with this technique it can be difficult to avoid being led into making unguarded statements. The Code Committee agreed that the healthcare professional's statements were consistent with the information contained in the media statement, which the Code Committee considered to be consistent with the Code, and with the approved use of the product. The Code Committee also thought that the healthcare professional had tried to keep the conversation on the disease, rather than focussing on the product. The Code Committee noted that it was the interviewer's repeated attempts at spelling the product name that had resulted in over-emphasis on the product, and concluded that the healthcare professional was unable to prevent this.

The Code Committee discussed whether media training is provided to key opinion leaders recommended by companies. The company representatives in attendance noted that it is provided where necessary. A number of the Committee members felt that media training could potentially been construed as indoctrinating a spokesperson or biasing what should be an independent opinion.

The Code Committee remained concerned that the activity was direct to consumer advertising, as the end result of the media segment may be that patients would be encouraged to seek a prescription for a particular prescription medicine. However, the conduct of Sanofi and its representatives was consistent with the Code. The Code Committee requested the Secretariat to refer Sections 12.3 and 12.4 to the Code Review Panel to consider making it clearer that direct to consumer promotion must be avoided if product specific media releases and interviews with spokespeople identified by companies are permitted. The Code Committee also requested that the Code Review Panel consider whether providing media coaching to key opinion leaders identified as spokespeople would be regarded as inappropriately influencing the independence of a healthcare professional.

The majority of Code Committee members were of the opinion that the end result of this segment was the promotion of a prescription product to the general public; however no breach of the Code could be found because Sanofi and its communications agency

had acted within the bounds of the Code of Conduct. The Code Committee agreed that the Code does not govern the radio station or interviewer who conducted the interview with the healthcare professional. In a majority decision, no breach of Section 12.3 of the Code was found.

The Code Committee particularly noted that a pharmaceutical company is not absolved of responsibility for any expert it identifies as a spokesperson. Experts should be properly briefed on the company's responsibilities under the Code and potentially offered media training to assist the expert to avoid any communication that could be regarded as promotion to the general public. Further, any agency working for a company should be fully cognisant of the Code and the company should ensure that its responsibilities are complied with.

The Code Committee unanimously considered that Sections 12.5 and 12.7.1 were not relevant to the conduct examined as part of the complaint and no breach of the Code was found in relation to these provisions.

The Code Committee considered whether the conduct brought discredit to the industry. In a majority decision the Code Committee found no breach of Section 9.13 of the Code.

Decision
In a unanimous decision, the Code Committee found no breach of sections 9.1, 9.12, 12.5, or 12.7.1 of the Code of Conduct. Additionally, the Committee found by majority decision no breach of sections 9.13, 12.3 and 12.4.

Appeal
The complainant appealed the decisions to find no breach of Sections 12.3, 12.4 and 9.13 of the Code. The complainant argued that the media release, media alert and background document, issued by Sanofi under embargo until 14 June 2011, contained promotional statements. The complainant argued that the purpose of these documents was to promote Actonel EC to the general public and resulted in the interview on radio 6PR with a healthcare professional which promoted a prescription medicine to the general public. The activity was therefore alleged to be in breach of Sections 12.3 and 12.4 of the Code. The complainant also argued that Sanofi had failed to properly brief the healthcare professional on the requirements of Section 12.3 and 12.4 of the Code and that Sanofi was therefore in breach of Section 12.4 of the Code.

The complainant further argued that the failure of Sanofi to disclose that it had a relationship with the healthcare professional brought the industry into disrepute and was therefore in breach of Section 9.13 of the Code.

Response to the Appeal
Sanofi reaffirmed its response to the complaint to the Code of Conduct Committee. Sanofi considered that its media release, media alert and background document were fully compliant with the Code. The media release and media alert were current, accurate and balanced and did not make comparisons with other products. Sanofi further argued that the healthcare professional is a respected clinician in his field and no payment was made to him for the media interview. Sanofi's relationship with the healthcare professional

reflected a common interest in management of osteoporosis.

Sanofi contended that in issuing a product specific press release, as is permitted by the Code, the company cannot control or be held accountable for the questioning style of a journalist. Sanofi argued that its conduct was consistent with the Code and supported the Code Committee's findings of no breach of the Code.

Consideration of the Appeal

The Chairman outlined for the Appeals Committee the process by which the complaint was originally sent to Medicines Australia. He noted that the complaint was originally lodged with the TGA, and that the complainant had requested confidentiality throughout the process. Following the Code of Conduct Committee's decision, the complainant chose to appeal. As the complainant was unable to attend the appeal hearing in person they had requested to be represented by two independent representatives, Dr Ken Harvey and Mr Eran Segev.

Prior to the complainant and Sanofi representatives joining the meeting the Appeals Committee had a brief in camera discussion to clarify the matters subject to appeal.

The representatives of both parties joined the meeting and were introduced to the Appeals Committee.

The Chairman explained the process for an appeal hearing to both parties and noted that an appeal is a re-hearing of the decisions made by the Code of Conduct Committee. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error. The Appeals Committee may then set aside or vary the decision and any sanction imposed. The Chairman noted that it would constitute procedural unfairness if the appeal went beyond those matters identified in the complaint and appeal submissions and the Subject Company had not had the opportunity to respond to any such matters. The Chairman also reinforced the confidentiality of the hearing and requested that both parties maintain those principles until such time as the Appeals Committee's decision and reasons for the decision of the meeting are provided to the parties.

The Chairman then invited the Appellant's representatives to present the appeal to the Appeals Committee. The following is a summary of that presentation:

Dr Harvey noted that a pharmacist heard an interview with a healthcare professional on 6PR Radio in Perth on 14 June 2011 on the drive time segment hosted by Mr Howard Sattler. The pharmacist was of the opinion that the interview was advertising the prescription product Actonel EC to the general public.

The pharmacist made a complaint to the TGA on the premise that the interview had breached the *Therapeutic Goods Act 1989* which prohibits the advertising of prescription products to members of the general public. Dr Harvey advised the Appeals Committee that the complainant was not originally concerned about a breach of the Medicines Australia Code of Conduct, but was more concerned about what they considered to be a serious breach of the legislation. However, the TGA had forwarded the complaint to Medicines Australia to consider whether there had been any breaches of the Code.

Dr Harvey noted that in the reasons for decision from the Code Committee, the majority of the Committee had agreed that the activity resulted in the advertising of a prescription product to the general public. However, the Code Committee found that the media release issued by Sanofi was compliant with the Code. No breach of the Code had been found because the Code does not govern a radio station or interviewer. The Code Committee did note that expert spokespeople must be properly briefed on the company's responsibilities under the Code. Dr Harvey argued that the media release was not compliant with the Code of Conduct and that any activities which resulted from its release were also not compliant with the Code of Conduct.

Dr Harvey further argued that Sanofi and its communications agency would have been aware of the interviewing style of Mr Sattler. Dr Harvey stated that there should be disclosure of relationships, whether between the spokesperson and the sponsoring company, or the sponsoring company and the interviewer. He acknowledged that there was no commercial relationship between Sanofi and Mr Sattler or radio 6PR, but it would have been appropriate for Sanofi to have informed Mr Sattler that prescription medicines must not be promoted to the general public. Dr Harvey acknowledged that this is not currently a requirement of the Code of Conduct and recommended that the Code Review Panel consider this during the Code review process.

Dr Harvey noted that the medical spokesperson had a relationship with Sanofi and had been selected by Sanofi to be interviewed. Dr Harvey noted that Sanofi has a responsibility to ensure that medical spokespeople are properly briefed on the Code and the Therapeutic Goods Legislation. Specifically, Sanofi had the responsibility to ensure that the healthcare professional was aware that promotion of prescription products to the general public is prohibited and should be avoided during any interview. Dr Harvey argued that the failure to provide adequate briefing was a breach of the Code by omission.

Dr Harvey turned to the media release and media alert that had been issued by Sanofi. The Code Committee found the media release and alert to be compliant with the Code and found no breach in its decision. However, Dr Harvey argued that the media release contains a number of promotional claims, as were itemised in the appeal document, which are expressly prohibited by Section 12.4.1 of the Code. He argued that without the media release and without the involvement of the communications company the interview on 6PR would not have occurred. Therefore Sanofi bears some responsibility for the interview, which the Code Committee found resulted in promotion to the general public.

Dr Harvey stated that the TGA has delegated the Code Committee to determine whether there was a breach of the Therapeutic Goods Act. He acknowledged that the Medicines Australia Secretariat had assisted the complainant in formulating the complaint so it could be evaluated against the Code of Conduct. The Code Committee found that a breach had occurred through the promotion of a prescription medicine to the general public. However, having found no breach of the Code by Sanofi the Code Committee took no further action. Dr Harvey argued that the Code Committee had some responsibility to

refer the matter back to the TGA or the ACCC to inform them of the breach of the legislation.

Dr Harvey closed the appeal presentation by asking the Appeals Committee to reconsider the media release and the activities that stemmed from it and find a breach of Sections 9.3, 12.3 and 12.4 of the Code of Conduct.
Sanofi representatives then provided their response to the Appeal.

Sanofi noted that they represented both Sanofi and Warner Chilcott at the appeal as co-marketers of Actonel EC. Sanofi consider that the Code of Conduct Committee was correct in finding no breach of Sections 12.3, 12.4 and 9.13 of the Code.

Sanofi addressed the provision of gifts by its communications agency to the healthcare professional. Following an internal investigation, it was discovered that individual(s) at Sanofi had been aware that the communications agency intended providing a thank you gift following the interview, which is inconsistent with the Code and company policies. The individual(s) have undertaken corrective action. Sanofi also contacted the healthcare professional, advising him that the provision of the wine and chocolates following the interview was not appropriate and would not be provided after any future engagements. The healthcare professional advised Sanofi that he did not receive any gifts. Sanofi accepts that it was incorrect to provide, or intend to provide, a gift to a healthcare professional. Sanofi also informed the healthcare professional of the complaint and that his identity may be made public following the finalisation of the complaint.

Sanofi then responded to the appeal in relation to Section 12.4 of the Code. Sanofi reiterated that the Code Committee determined that the media release was not in breach of the Code. Sanofi argued that the media release does meet the requirements of section 12.4 as it was released at a time point that is acceptable under the Code, contains the required safety and precaution information, and provides a link to the Consumer Medicine Information. Sanofi asserted that the media release is balanced, accurate and meets the standards as set by the Code of Conduct. Sanofi responded to the complainant's submission, that the media release does not make any references to alternative treatments. Sanofi contend that by doing so it would be comparing treatment options, which is prohibited by Section 12.4. Sanofi instead chose to focus the release on the Government's decision to list the product on the PBS.

Sanofi further consider that the media release is consistent with the Code requirement for adhering to community standards. Sanofi stated that the information on bisphosphonates and osteoporosis were referenced to the Osteoporosis Australia website, which refers to the relative benefits of all products. Sanofi therefore consider that the media release is consistent with community standards.

Sanofi agreed with the complainant that the company is responsible for their agents. Sanofi confirmed that its contracts with agents state that industry requirements must be upheld at all times. Sanofi selected the communications agency to represent its interests as they are experienced in, and solely focus on, the healthcare industry. Sanofi stated that the communications agency have a standard process briefing

spokespeople on the Code of Conduct and their obligations when representing Sanofi.

Sanofi advised that they believed that the healthcare professional's actions during the interview were compliant with the Code of Conduct. Sanofi noted that the healthcare professional had only used the product name in response to a direct question from Mr Sattler. Sanofi further noted that the healthcare professional attempted to discuss osteoporosis in his responses rather than speaking only about the product. Sanofi also noted that in his responses, the healthcare professional referred members of the general public to their healthcare professionals to discuss the condition rather than the specific product.
Sanofi advised that neither it, Warner Chilcott nor the communications agency have a financial arrangement with the healthcare professional, Radio 6PR or Mr Howard Sattler. Sanofi advised that following the media release being issued, 6PR had contacted the communications agency asking for an interview, and communications agency put them in touch with the healthcare professional. Neither Sanofi nor the communications agency is in the position to prescribe which questions a journalist asks. Sanofi issued the media release as a genuine media activity and not a promotional activity.

Sanofi advised the Appeals Committee that it was not its intention to mislead by not disclosing any relationship it had with the healthcare professional; however Sanofi noted that it has met all obligations as described in the current Code of Conduct. If the Code is changed in the future, Sanofi will comply with any disclosure or transparency requirements. Sanofi does not consider that the healthcare professional's responses in the interview have been compromised or biased by his previous relationship with Sanofi in co-authoring papers relating to osteoporosis management.

In closing its presentation, Sanofi contended that the activity it undertook was in line with the Code of Conduct and therefore could not bring the industry into disrepute. Sanofi believe that it acted responsibly and engaged appropriately with the general public. Sanofi reiterated that it was within its rights to issue the media release. Sanofi acknowledged that the communications agency had erred in providing the healthcare professional with gifts following the interview, however they emphasised that the gifts were not provided with the intention of influencing the interview (as this occurred after the event) and it had acted to prevent this happening in the future.

A member of the Appeals Committee asked Sanofi whether the healthcare professional was given a briefing on the Code and its requirements prior to the interview. Sanofi advised that the communications agency have a standard protocol which is to provide a briefing to each spokesperson on the Code. This includes a briefing to maintain focus on the message contained in the media release, including balanced and educational information not promotional statements. Sanofi advised that the provision of such a briefing is not documented.

A member of the Appeals Committee questioned whether Sanofi had considered choosing a medical expert who was more independent than the one selected. Sanofi responded that the selection of the healthcare professional as the spokesperson was

appropriate. Sanofi noted that it works with a large number of healthcare professionals and believe that their interactions are appropriate, compliant with the Code of Conduct and do not compromise either party.

A member of the Appeals Committee questioned what information was provided to 6PR and specifically Mr Sattler. Sanofi responded that the communications agency had communicated to 6PR via email. The only materials provided to 6PR were the media release, media alert and, following a further request and the healthcare professional's biography. The Appeals Committee noted that at no point in this correspondence was the Code of Conduct mentioned to 6PR.

The Chairman questioned if any other activities had resulted from the media release. Sanofi advised that 254 television events, 23 online articles, 8 print articles and 24 radio articles had occurred. However Sanofi also noted that many of these would have been the same item repeated at different times throughout the day on the various media. The 6PR interview was the only event where concerns have been raised. Sanofi noted that the healthcare professional was interviewed twice, with the other interview being a cut-down version of a longer interview and that it had focussed on the government listing of the product.

One Appeals Committee member questioned why Sanofi considered that the media release did not contain promotional statements. Sanofi contended that the media release contained educational information relevant to the PBS listing of the product and the reasons for that decision – the reasons the product was approved by the TGA and PBS listed. The Appeals Committee questioned Sanofi if the reasons for these decisions are publicly available. Sanofi advised that the information published by the PBAC is a summary document, not detailed information. The relevant information would be found in the Product Information, which is referenced in the media release.

The Chairman asked whether Sanofi accepted that the healthcare professional went outside the scope permitted by the Code. Sanofi disagreed with that statement and reiterated that it believed that the healthcare professional did his best against a particularly leading line of questioning and had endeavoured to keep the interview on message.

Sanofi concluded by reiterating that it considers that the media release was non-promotional and non-comparative and therefore any activities stemming from it could not be found in breach of the Code.

Following this presentation, Dr Harvey made his closing statement on behalf of the Appellant:

Dr Harvey challenged the Appeals Committee to determine that the media release was promotional. Dr Harvey questioned whether the activity would have been in breach if the medical expert was completely independent of Sanofi; in his opinion it would not be. He also noted that the brand name was used 15 times in the seven-minute interview, and he questioned what would be deemed an appropriate use of the brand name. He contended that a brand name should not be mentioned at all and that the active ingredient name, rather than the brand name, of a product should be used.

Dr Harvey urged the Appeals Committee to hold someone accountable for the promotion of a prescription product to the general public, which the Code Committee acknowledged had occurred. Sanofi has responsibility for not properly briefing the healthcare professional to avoid promoting the product in the interview. He recommended that the Code of Conduct review incorporate the requirement that a statement to the effect of "promotion of a prescription product to the general public must not occur" be included at the footer of each media statement issued to lay media.

Dr Harvey also noted that there is a general move globally towards the declaration of conflicts of interest. Dr Harvey argued that healthcare professionals who have financial relationships with industry tend to be more favourable and positive about specific products and less likely to give balanced information. Declaration of conflicts of interest should be required. The end result of the interview was promotion of a prescription medicine to the general public and the industry was brought into disrepute.

Sanofi responded to this comment, stating that it did not agree that the healthcare professional's comments were unbalanced or promotional.

Both parties then left the meeting and the Appeals Committee commenced its deliberation.

The Appeals Committee agreed that the issues raised by the Appellant's representative relating to transparency and disclosure of conflicts of interest were outside the scope of this Appeal. The Secretariat advised the Committee that these issues were raised in several submissions to the Code of Conduct Review and are therefore under active consideration by the Code Review Panel.

The Appeals Committee reviewed the media release and media alert that were issued by Sanofi in June 2011. The Appeals Committee considered that the Code Committee had erred in finding that the media release and media alert were not promotional. The Appeals Committee considered that a number of statements in the media release were promotional, as had been identified by the complainant in the appeal submission. The Appeals Committee noted that in the Consumer Media Alert the statement *"...another option to help reduce the rates of fracture and early death associated with this insidious disease"* was not consistent with Actonel EC's Product Information because the product is not indicated for a reduction in death rates from osteoporosis. Further, the Appeals Committee considered that the media release and media alert both contained statements that exaggerated the benefits of the product. The Appeals Committee noted that the studies used to support these claims show that Actonel EC has an equivalent efficacy and adverse events when compared to other bisphosphonates. The terms "innovative", "novel" and "important advance" were promotional and overstated the benefit of an enteric coated dosage form.

The Appeals Committee agreed that the quotes contained in the media release from two medical experts were also promotional. Specifically, the Appeals Committee agreed that the statements *"without the special enteric coating and calcium binding agent of Actonel EC, eating breakfast or even drinking a simple cup of coffee of glass of juice at the same time would significantly reduce the absorption of*

the medication..." and *"With Actonel EC people with osteoporosis requiring a bisphosphonate tablet can still have breakfast and have optimal fracture protection"* were promotional. The Appeals Committee determined that the media release had not satisfied the provisions of Section 12.4 of the Code and therefore agreed by unanimous decision that the media release was in breach of the Code.

The Appeals Committee agreed that the explanation of the briefing provided to the healthcare professional prior to the interview and the lack of evidence as to the content of the briefing was unsatisfactory. The Appeals Committee considered that the healthcare professional had been led by Mr Sattler's questioning throughout the interview, which resulted in promotion of the product to the general public. If the healthcare professional h had been properly briefed on the Code and the requirement to avoid any promotion of the product this would have been avoided. The Appeals Committee determined that the radio interview on 6PR was the culmination of Sanofi issuing the consumer media release and media alert for Actonel EC. Sanofi, through its communications agency, had identified the healthcare professional as a medical spokesperson available for interview; the interview on 6PR had resulted in promotion of a prescription product to the general public. The interview by Mr Sattler would not have progressed in that way if the media release had been framed in a non-promotional manner. Sanofi had failed to ensure that the medical spokesperson it had nominated for interview was adequately briefed on the requirements of the Code. The Appeals Committee considered that the Code Committee was in error in not attributing responsibility to Sanofi for the outcome. The Appeals Committee agreed by unanimous decision that Sanofi was in breach of Section 12.3 of the Code of Conduct.

The Appeals Committee determined that the activity did not generate any further media attention following the interview and therefore agreed by unanimous decision that it was not in breach of Section 9.13.

With regard to the Appellant's question as to why the complaint was not referred back to the TGA following the Code of Conduct Committee's initial determination, the Chairman noted that the relationship between the TGA and Medicines Australia is informal and not a delegation in legislation or regulation. The Appeals Committee agreed that the determination of the Committee finalised the complaint as it relates to the Medicines Australia Code of Conduct. However, the Appeals Committee noted that it remained open to the complainant to pursue the matter with the TGA if they chose.

Sanction

The Appeals Committee considered that the breaches of Sections 12.3 and 12.4 of the Code of Conduct were moderate because they would have no impact on a patient's wellbeing but may influence prescribing by healthcare professionals. The Appeals Committee agreed that there was no opportunity to correct the activity; only to prevent it from recurring.

The Appeals Committee agreed that the media release and media alert issued by Sanofi must not be re-issued at any time. The Appeals Committee determined that if these media statements are available on a public website, Sanofi must remove them immediately. The Appeals Committee determined that Sanofi must cease

using the promotional statements contained in the consumer media release in communications with the general public and they should not be used in similar materials directed to the general public or lay media.

The Appeals Committee determined by unanimous decision that each breach should be considered individually and agreed that a sanction should be applied to each breach. The Appeals Committee agreed by unanimous decision that the breach of Section 12.3 should incur a fine of $20,000 and that the breach of Section 12.4 should also incur a fine of $20,000, bringing the total sanction to $40,000.

The Appeals Committee also instructed Sanofi to provide the Reasons for Decision for this complaint to both the healthcare professional who was interviewed and Mr Sattler.

Vote Against Stroke Website – 1079

Subject Company: Boehringer Ingelheim

Complainant: NSW Therapeutic Advisory Group

Activity: website voteagainststroke.com.au (relating to Pradaxa)

Complaint
The NSW Therapeutic Advisory Group (NSW TAG) alleged that the content of a public website, both in its original form and amended form, published by Boehringer Ingelheim was in breach of the Code.

NSW TAG argued that the content of the information on the website, including content in embedded videos, constituted advertising in that it included statements which were intended to promote the use and supply of a prescription product.

Sections of the Code
The activity is alleged to be in breach of the following Sections of Edition 16 of the Code:

- 12.3 Promotion to the general public
- 12.8 Use of the Internet
- 12.9 Social Media

Response
Boehringer Ingelheim denied that the website was intended to promote Pradaxa to the general public. It argued that there was no mention of any product name on the website. The intent of the website was to inform doctors and patients of the Government's decision, contrary to the advice of the PBAC, to delay the listing of a new stroke medication. The content of the website was changed on 21 November 2011; at this time the company's ownership of the website was made more prominent.

Code Committee decision

- The Committee determined by majority decision that version 1 of the website was in breach of Sections 12.3, 12.8 and 12.9 of the Code of Conduct.
- The Committee determined by majority decision that version 2 of the website was not in breach of Sections 12.3, 12.8 or 12.9 of the Code of Conduct.

<u>Sanction</u>
The Committee imposed a fine of $125,000.

Consideration of the complaint
The Committee discussed whether the activity to encourage members of the health profession and consumers to petition the government came under the scope of the Code of Conduct. The Committee agreed that the use of the internet by companies to communicate with the general public or health professionals did fall within the Code, and in particular where such communication related to availability of prescription medicines and potentially promotion to the general public. The Committee agreed that activity had the potential to set a precedent and requested that the matter be referred to the Code Review Panel to consider including specific guidance on this type of lobbying activity in the next edition of the Code of Conduct.

The Committee noted that two versions of the website were under consideration in this complaint. The first version of the website was available from 3 November 2011 until 20 November 2011 and the modified version available from 21 November 2011 to the present. Boehringer Ingelheim had stated in its response that the website was modified in response to an enquiry from the Therapeutic Goods Administration (TGA).

<u>Website version 1 – Available 3 November 2011 – 20 November 2011</u>
The Committee accepted that the primary purpose of the website was to encourage healthcare professionals and members of the general public to petition the Government to reverse its decision to defer the listing of a particular product to prevent stroke in people who have atrial fibrillation. The Committee acknowledged that the Government's deferral of listing of a range of medicines was of concern for companies, healthcare professionals, PBAC members and members of the general public. However Committee was of the opinion that the website published by Boehringer Ingelheim was not consistent with the Code.

The Committee considered that the language in version 1 of website was highly emotive and inflammatory and would create alarm and concern in members of the public. The Committee particularly noted the language such as "Australia is facing an epidemic of stroke" in people with atrial fibrillation and "this decision could be a matter of life or death for many thousands of elderly Australians with atrial fibrillation". The Committee noted that the website did not include any safety information or potential side effects of the new medicine. The Committee considered that the website encouraged people to seek prescription of the new medicine because it gave a general public reader the impression that there were no other treatments available on the PBS or only "less effective medicines", which added to the creation of fear that the community was experiencing a stroke "epidemic".

The Committee were concerned that the website did not include any information about who sponsored the website on any of its pages. The Committee were also concerned that the Pradaxa Product Information and the PBAC public summary document for dabigatran were used as references for claims about the benefits of the "21st century stroke prevention medicine", which thereby identified the particular product and contributed to the promotion of the product to the general public.

The Committee agreed that as access to this website was not restricted to health professionals only, but was

accessible to the general public, it may encourage patients to seek a prescription for a particular product from their general practitioner. Although the Committee accepted that an average consumer would not immediately identify the product by name, they would likely remember the messages from the website (such as "Demand 21st Century Stroke Prevention") when speaking with their general practitioner.
The Committee agreed by majority decision that the website available between 3 November 2011 and 20 November 2011 was in breach of Sections 12.3. The Committee further determined by majority decisions that the website version 1 was in breach of Sections 12.8 and 12.9 of the Code of Conduct because the website was a use of the internet and used social interaction to communicate with the general public in a promotional manner.

Website 2 – 21 November 2011 to the present

The Committee noted that the website had been substantially changed following enquiry from the TGA. The name of the company appears in the footer of each page and there is no reference to any product. The Committee found by majority decision that version 2 of the website was not in breach of Sections 12.3, 12.8 or 12.9 of the Code of Conduct.

Decision

The Committee agreed by majority decision that website version 1 was in breach of Sections 12.3, 12.8 and 12.9 of the Code of Conduct. The Committee agreed by majority decision that the amended website (version 2) was not in breach of Sections 12.3, 12.8 and 12.9 of the Code of Conduct.

Sanction

The Committee discussed the severity of the breaches. A minority of the Committee considered the breaches to be severe breaches of the Code and possibly bringing discredit to the industry, although it was acknowledged that this was not alleged by the complainant. The majority of the Committee considered the breaches to be in the moderate category, there being no safety implications for patients but the activity may have an impact on how health professionals will prescribe the product as a result of encouraging members of the general public to seek a prescription for a specific medicine.

The Committee determined that Website version 1 must not be reinstated or made available on the internet at any time in the future. Boehringer Ingelheim must maintain its discontinuation.

The Committee questioned what information would be provided to those healthcare professionals and members of the general public who had signed the online petition or who had signed up on the 'keep me updated' facility and who had submitted to their personal information. The Committee considered that any information provided by Boehringer Ingelheim to consumers or health professionals from this database would be inappropriate because the website was found in breach of the Code and determined that Boehringer Ingelheim must not use the names and contact details that have been gathered through this activity.

The Committee imposed a fine of $125,000.

Appeal
The Complainant appealed the decisions finding no breach of Sections 12.3, 12.8 or 12.9 of the Code of Conduct for version 2 of the voteagainststroke.com.au website.

NSW TAG argued that the intent of the second version of the website is unclear, as is how the results of the petition will be used. Despite Boehringer Ingelheim being identified as the copyright owners of the site, the company has not made any reasonable disclosure of its financial interest in the Government decision surrounding the listing of a new stroke medication, dabigatran, (Pradaxa®). The website does not explain why the petition is of current interest or suggest what action the Government should take to reduce the incidence of strokes associated with atrial fibrillation. The website also does not provide information on the Government review of anticoagulants

Appeal Response
Boehringer Ingelheim responded to the appeal stating it has taken every reasonable action to limit any potential for misinterpretation of the content or purpose of the website. Boehringer noted that these actions were taken prior to the complaint lodged by NSW TAG, and were implemented rapidly. While Boehringer Ingelheim still considers that version 1 of the website met the Code requirements, and this website was live for just 18 days, it had accepted the Code Committee's decision and sanctions both in regard to version 1 and version 2 of the website. Version 2 of the website, which was not found by the Code Committee to have breached the Code, contains no mention or promotion of any prescription product and therefore Boehringer strongly believes that it meets all Code requirements.

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

The Chairman explained the process for consideration of an appeal to Boehringer Ingelheim's representatives and noted that an appeal is a re-hearing of the decisions made by the Code of Conduct Committee. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error. The Appeals Committee may then set aside or vary the decision and any sanction imposed. The Chairman noted that it would constitute lack of procedural fairness if the appeal went beyond those matters identified in the complaint and appeal submissions and the Subject Company had not had the opportunity to respond to any such matters.

The Chairman noted that the complainant had appealed the Code Committee decision that the revised website (Version 2) was not in breach of the Code, and further noted that the findings in relation to the original website (Version 1) were not open for discussion.
The Chairman then invited Boehringer Ingelheim to make its presentation to the Appeals Committee. The following summarises that presentation:

Boehringer Ingelheim advised that it wished to address some misconceptions in the NSW TAG submission regarding the timeline for the approval of Pradaxa and the inception of both websites. Firstly,

Boehringer noted that the Therapeutic Goods Administration (TGA) has introduced parallel processing allowing both TGA and Pharmaceutical Benefits Advisory Committee (PBAC) processes to occur in parallel. Previously products had to be approved by the TGA before being considered by the PBAC for listing on the Pharmaceutical Benefits Scheme (PBS). Pradaxa was one of the first products to be considered through parallel processing.

Boehringer Ingelheim outlined the timeline of events in relation to the listing of Pradaxa, the inception of the websites, the NSW TAG complaint and other relevant factors:

Mar 2011	PBAC recommended Pradaxa be listed on the PBS
Apr 2011	TGA approved Pradaxa for the prevention of stroke in patients with non-valvular atrial fibrillation (AF)
30 Sept 2011	Cabinet announced further review of anticoagulants, to be chaired by Emeritus Professor Lloyd Sansom
3 Nov 2011	Vote Against Stroke Website launched (Version 1); one week later TGA Office of Product Review (OPR) raised concerns with Boehringer
21 Nov 2011	Vote Against Stroke Website amended following discussion with the OPR (Version 2 instituted)
30 Nov 2011	Boehringer Ingelheim received complaint lodged by NSW TAG
22 Dec 2011	Terms of Reference released for the Review of Anticoagulants.

Boehringer Ingelheim also advised the Appeals Committee that the decision to list Pradaxa on the PBS, following a positive recommendation from the PBAC, had been deferred by the Federal Government.

Boehringer Ingelheim noted that the version 1 website was launched seven weeks prior to the release of the terms of reference or any other information pertaining to the anticoagulant review, which was announced by the Federal Government in September 2011.

Boehringer Ingelheim provided the Appeals Committee with context for consideration of PBS listing of Pradaxa, noting that AF patients are five times more likely to experience a stroke and that 70% of patients presenting to hospital with an AF-related stroke were not taking anticoagulants. Boehringer Ingelheim stated that the intent of the website was not to promote any product but to simply provide a vehicle for healthcare professionals and patients on Pradaxa to comment to the Government on anticoagulant issues in light of the Government deferral of listing the product. The Code of Conduct Committee had accepted that the primary purpose of the website was to encourage health professionals and patients to petition the Government. Boehringer Ingelheim noted that all comments through the website were provided directly to the Federal Government; no filtering occurred.

An Appeals Committee member questioned how members of the general public would find the website. Boehringer Ingelheim responded that it had communicated with all physicians and patients involved in the Pradaxa Product Familiarisation Program (PFP) and that the website was accessible to all members of the general public and could be easily found using any internet search engine. Boehringer

Ingelheim noted that the PFP had recruited a large number of patients, however it had not commenced until the PBAC had made its positive recommendation. Boehringer Ingelheim noted that in the period 20 November 2011 to 17 February 2012 version 2 of the website had received just over 1000 hits.

Boehringer Ingelheim representatives stated that they considered that the fine for version 1 of the website imposed by the Code Committee was excessive and not in line with other fines for similar conduct. Boehringer Ingelheim had taken care to not directly advertise a prescription product to the general public and did not mention any product name on either site. Nevertheless Boehringer Ingelheim had accepted the Code Committee's decision.

Boehringer Ingelheim then addressed the issues raised in NSW TAG's Appeal Submission:

Rhetorical statement

NSW TAG alleged that the statement *"help the federal government understand the need for action to reduce the number of strokes suffered by Australians with an irregular heartbeat, known as Atrial Fibrillation"* was rhetorical and did not provide a rationale for why the petition is of current interest or suggest what the Federal Government should do to reduce the number of strokes resulting from AF.

Boehringer Ingelheim argued that a less rhetorical, more explicit statement might have been in breach of the Code. The site contained no product information, nor a product brand name; inclusion of this explicit information would have been considered to be promotional and therefore in breach of the Code. Further, rhetorical statements are not prohibited by the Code.

Department of Health and Ageing (DoHA) Review

NSW TAG alleged in its response that the website had been activated 2 months after the announcement of DoHA's review of the role of anticoagulants in AF.

Boehringer Ingelheim reiterated the timeline of events as previously noted; the website was actually created 2 months after the review had been announced, but this was more than seven weeks prior to the terms of reference or any details of that review being released.

Disclosure of financial interest

NSW TAG noted in its response that although website version 2 identifies Boehringer Ingelheim as copyright owner of the site and provides its contact details, there is no reasonable disclosure of Boehringer Ingelheim's financial interest in the Government decision surrounding the listing of dabigatran.

Boehringer Ingelheim responded that it stands by website version 2 as being clear that the site is owned and maintained by Boehringer Ingelheim Pty Ltd, and that this information appears on every page of the website. Boehringer Ingelheim reiterated that if a product name had been mentioned, this would have constituted promotion.

Information regarding serious adverse events

NSW TAG noted in its response that website version 2 lacked any information regarding serious adverse events associated with the use of new oral anticoagulants, including dabigatran, and other limitations such

as the inability to reverse anticoagulation in emergency situations.

Boehringer Ingelheim reiterated that all oral anticoagulants have side effects and adverse events. Again, Boehringer Ingelheim stood by its decision that to include this information about a specific product would have constituted promotion and would have therefore been in breach of the Code.

Sanctions

In its submission, NSW TAG requested that the Appeals Committee impose the same sanctions on website version 2 as the Code Committee imposed on website version 1.

Boehringer Ingelheim advised that website version 2 did not gather signatures via a petition; rather emails were generated directly to the three people identified on the site. A respondent may choose who an email is sent to, with no interference from Boehringer Ingelheim.

Further, Boehringer Ingelheim argued that website version 2 does not contain promotion to the general public and therefore no sanction should apply.

Boehringer Ingelheim summarised its presentation:

- The intention of the site was not to promote a product. The Code Committee found differently, but Boehringer Ingelheim is not contesting that decision.
- The Code Committee had agreed that the deferral issue was a major concern – supported by consumers and Medicines Australia.
- Rapid action was taken following initial concerns raised by OPR (TGA).
- Sanctions imposed for website version 1 appear to be at odds with precedents for similar activities.
- Website version 2 contains no promotion of a particular product and does not breach the Code.

One Appeals Committee member questioned Boehringer Ingelheim whether the comments gathered via the website would feed directly into the Federal Government's anticoagulant review. Boehringer Ingelheim advised that it had recently met with the chairman of the review panel, Emeritus Professor Lloyd Sansom. Professor Sansom agreed that consumers should have an active role in making their views known to the review panel, however the review would rather hear this through patient groups and individuals, as opposed to through company websites.

The Chairman then thanked Boehringer Ingelheim for its presentation and the company representatives left the meeting. The Appeals Committee then commenced its deliberations.

The Chairman reiterated to the Appeals Committee that the appeal was only in relation to website version 2 and therefore it must be considered in isolation of website version 1.

The Appeals Committee discussed who could access website version 2, noting that it could be accessed by any member of the general public. The Appeals Committee agreed that if the site had been only accessible to healthcare professionals and patients who were already prescribed the product as part of the Product Familiarisation Program, promotion to the general public wouldn't have been

as much a concern. However, this website is widely accessible to all members of the public through a simple internet search engine, which indirectly promotes the product to those people who are not taking it.

The Appeals Committee considered that the revised version of the website (version 2) provided neither education nor information and sought to harness representations to government by people who have no information about the background to the petition or the company's financial interest in the issue. The website evidently did not achieve the outcomes Boehringer Ingelheim intended. The chairman of the anticoagulant review has reportedly stated that the review panel was not interested in any submissions from the site but wished to receive consumer input directly. The Appeals Committee noted that the number of visits to the website was low.

The Appeals Committee considered that the limited information on the site encouraged members of the general public to make a submission or sign a petition without being given relevant information such as Boehringer Ingelheim's interest in getting Pradaxa listed on the PBS – the action required of Government "*to reduce the number of strokes suffered by Australians with an irregular heart beat, known as atrial fibrillation*". The Appeals Committee considered that the website was indirectly promoting the product Pradaxa to those members of the general public who were not already prescribed dabigatran. The Committee agreed that if the website had been contained to healthcare professionals and PFP enrolled patients only, the website may not have been in breach of the Code.

The Appeals Committee noted that there was wide media attention for the product when it was approved by the TGA and the PBAC summary is publically available. Therefore, members of the general public would be aware of which product is the subject of the required Government action.

The Appeals Committee agreed by majority decision that website version 2 was in breach of Sections 12.3, 12.8 and 12.9 of the Code of Conduct because it was indirectly promoting a prescription medicine to the general public by not restricting the site to the PFP participants and healthcare professionals. By virtue of enrolment in the PFP, patients have sufficient information to make an informed decision about participating in the petition. The Appeals Committee agreed that members of the general public who accessed this site through an internet search would not have access to that information. The website amounted to promotion to those people who accessed the website who were not already prescribed dabigatran. The Committee considered that the breach should be classified as minor.

Sanction

The Appeals Committee determined by unanimous decision that no additional financial sanction should be imposed on Boehringer Ingelheim.

The Appeals Committee also unanimously determined that website version 2 should also be removed immediately. Further, the Appeals Committee determined that any information gathered through the website that is held by Boehringer Ingelheim must not be used in any manner.

Lexapro Promotional Materials – 1080

Subject Company: Lundbeck

Complainant: Healthcare professional

Product: Lexapro

Complaint
A healthcare professional alleges that material left by a Lundbeck representative in a hospital meeting room on 22 November 2011 is in breach of the Code of Conduct. The material uses the tag line "tick the box..." which is interpreted by this healthcare professional and their colleagues as encouraging prescribers to disallow generic substitution by the pharmacist.

The healthcare professional also alleges that the statement could also be interpreted that the Lexapro is superior to other products in its class. The healthcare professional notes that the TGA advises that all escitalopram products are bioequivalent and thus no single product could be expected to produce a superior clinical response over another.

Sections of the Code
The activity is alleged to be in breach of the following Sections of Edition 16 of the Code:
• 1.3 False and misleading claims

Response
Lundbeck submits that the promotional piece for Lexapro provides current, balanced and accurate information which is satisfied by the supporting references. Lundbeck notes that no mention or comparison to a generic product was made in the piece, and denies that any statement in the piece claims that Lexapro is more efficacious than a generic version.

Lundbeck denies that any comparison is made or implied that suggests that Lexapro is in some way superior and feels that the piece is not misleading.

Code Committee decision
The Committee agreed by unanimous decision that there was no breach of Section 1.3 of the Code of Conduct.

Consideration of the complaint
The Committee noted that the matter at the heart of the complaint is whether the term "tick the box" is an inducement for prescribers to prevent pharmacist switching patients to a generic brand at the time of dispensing, thereby blocking generic substitution.

The Committee agreed that the phrase "tick the box" is used by healthcare professionals when discussing substitution; however the Committee agreed that in this instance there was no inducement for prescribers to block generic substitution.

The Committee discussed the Complaints allegations that Lexapro is superior to other products in its class. The Committee noted that the Cipriani et al study used to support the comparison table on the piece showed that citalopram and escitalopram were treated as different drugs which was appropriate as citalopram is not a generic version of escitalopram.

The Committee appreciates how the complainant may have come to their interpretation of the promotional piece, especially the statement "tick the box". However the Committee agreed by unanimous decision that there was no inducement to block generic

substitution and no breach of Section 1.3 of the Code of Conduct was found.

Sanction
As no breach of the Code of Conduct was found, no sanction was levied.