Medicines Australia Code of Conduct Quarterly Report July – September 2019

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

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

This report covers all complaints finalised between April to June 2019. Complaints finalised during this period were in relation to materials or activities conducted under Edition 18 of the Code.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time.

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) 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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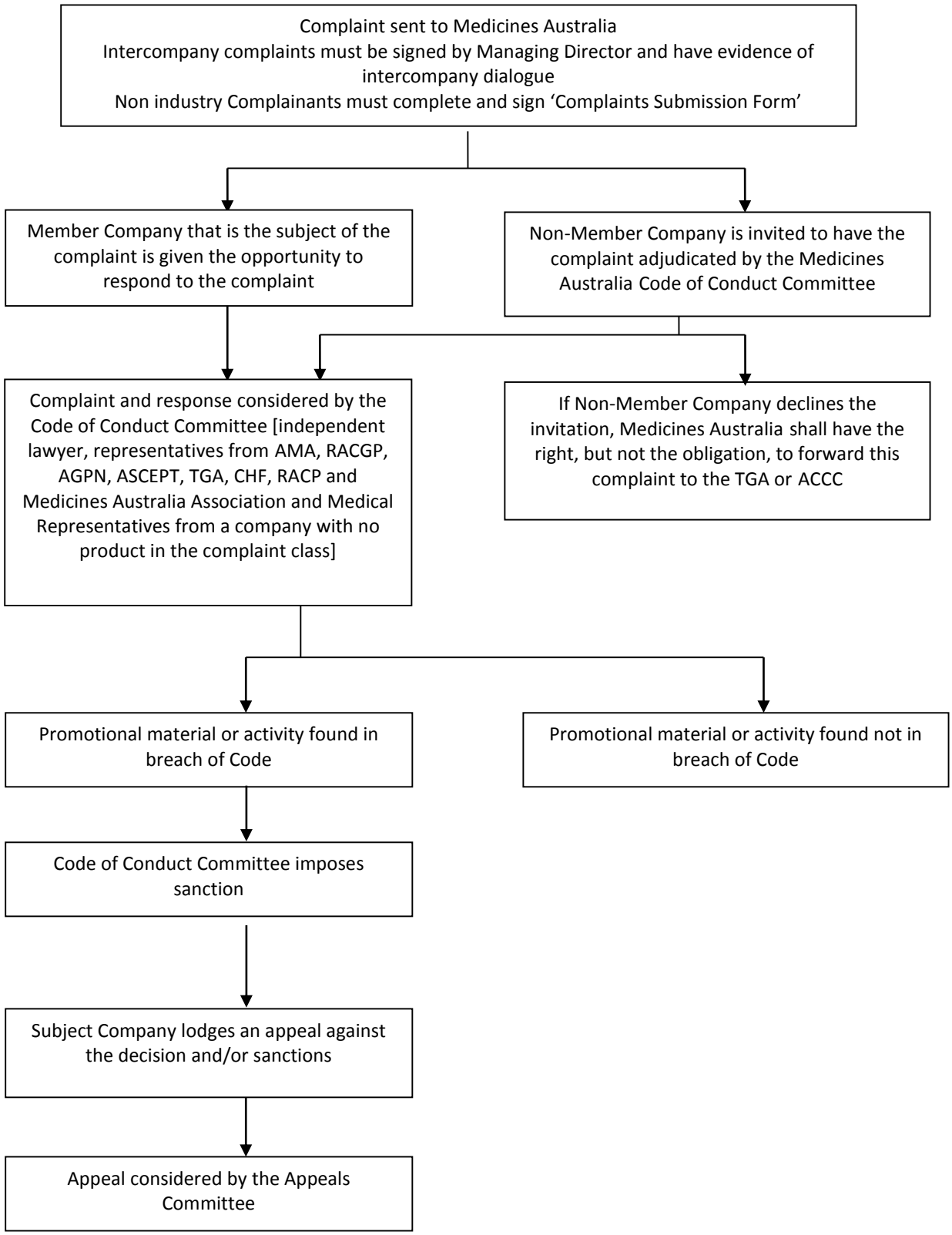
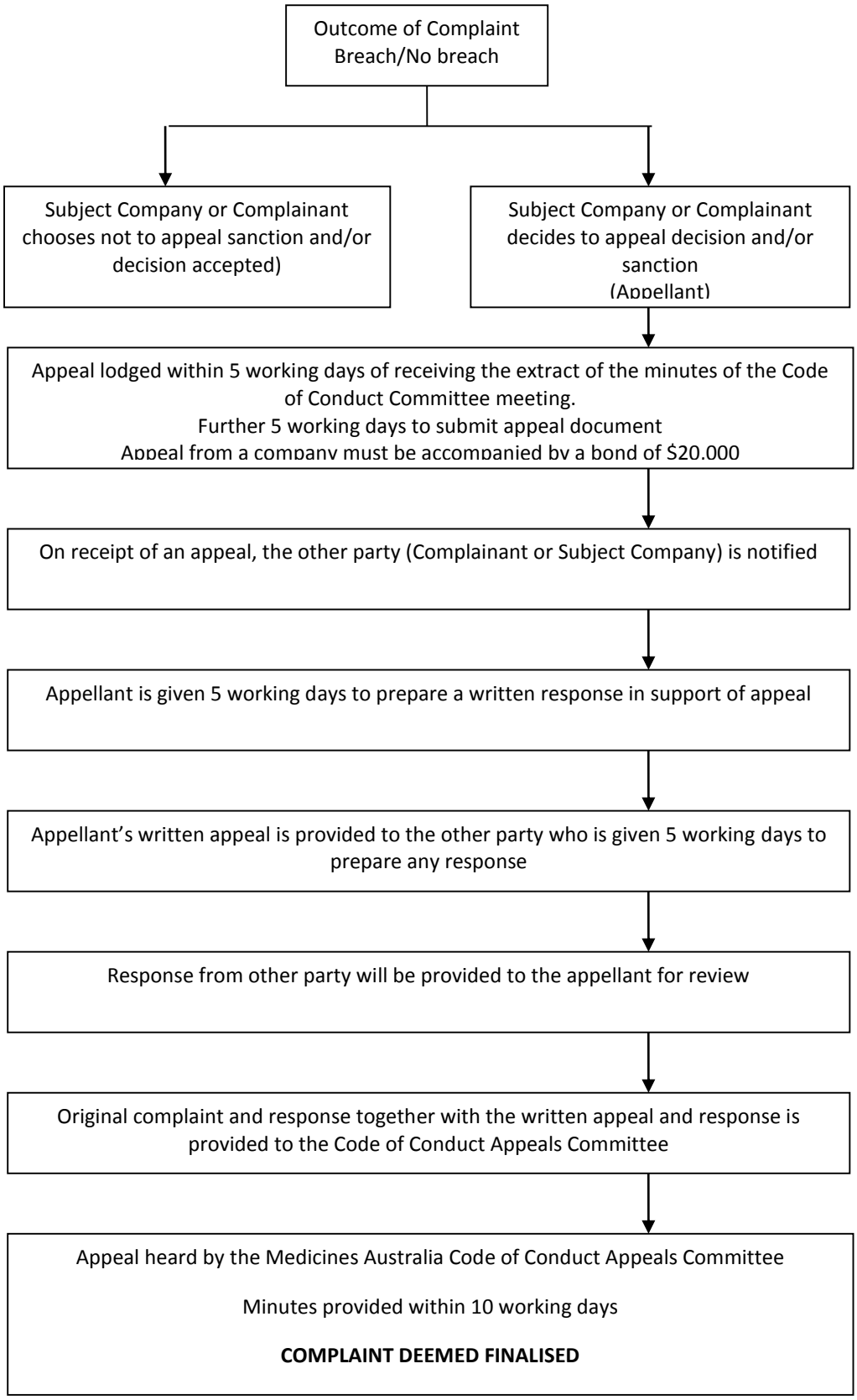
Medicines Australia Code of Conduct Complaints Handling Process



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 4 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 4 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 18 of the Code)

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

Table of finalised complaints April – June 2019

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1153	Sanofi-aventis Australia Pty Ltd (trading as Sanofi Pasteur)	Product Specific Media Statement	Fluzone® High-Dose (HD)	Seqirus (Australia) Pty Limited	Breach 13.4.1	Fine $100,000

Fluzone High Dose (HD) Media Release

Complaint	Subject Company	Product	Complainant
1153	Sanofi-aventis Australia Pty Ltd (trading as Sanofi Pasteur)	Fluzone High-Dose	Seqirus (Australia) Pty Limited (Seqirus)

Complaint
Seqirus had alleged that a consumer media release issued by Sanofi Pasteur on 7 March 2019 was in breach of the Code of Conduct because it was promoting to the general public the availability and positive attributes of a prescription product, Sanofi Pasteur's influenza vaccine Fluzone High-Dose.

Seqirus identified three claims within the media release, which it alleged were in breach of the Code of Conduct.

1. "Fluzone High-Dose has been clinically proven to protect against influenza and its complications such as hospitalisation among older adults,"
2. "We believe this is bad news for the older population who are at higher risk of developing serious complications from flu such as hospitalisation, pneumonia, heart attack or death,"
3. "We don't want to see a group that has an increased risk of developing influenza complications be denied fair access to this vaccine because it is not funded."

The first claim was alleged to go beyond the approved indication of Fluzone High-Dose and was alleged to be promotional, which is contrary to Section 13.4.1 of the Code. Claims 2 and 3 were alleged to be comparative, disparaging to Seqirus' product Fluad, inaccurate and misleading. Seqirus had contended that the media release implied superiority of Fluzone High-Dose over Fluad, which is also contrary to Section 13.4.1 of the Code.

Seqirus had alleged that the media release had the potential to adversely affect prescribing practice and thereby bring the pharmaceutical industry into disrepute.

Sections of the Code
The media release was alleged to be in breach of the following Sections of Edition 18 of the Code:

- Section 13.4.1 Product Specific Media Statements

Response
Sanofi Pasteur had rejected the allegation that the media release was in breach of Section 13.4.1 of the Code. Sanofi Pasteur stated in its response that each statement in the media release was current, factual and able to be substantiated. It argued that the media release did not contain any comparison with Fluad or any other influenza vaccine. It also argued that the media release was consistent with the approved Product Information for Fluzone High-Dose, whilst written in language appropriate for the intended audience.

In addition, Sanofi Pasteur argued that Seqirus had introduced materials that were directed at healthcare professionals, which were unrelated to the consumer media release subject to complaint. Sanofi Pasteur asserted that these materials should not be considered as part of the complaint.

Code of Conduct Committee decisions
The Code of Conduct Committee made the following decisions in relation to the claims in the Media Release:

- Claim 1: "*Fluzone High-Dose has been clinically proven to protect against influenza and its complications such as hospitalisation among older adults,"*

  The Committee found by majority decision that claim 1 was in breach of Section 13.4.1 of the Code.

- Claim 2: *"We believe this is bad news for the older population who are at higher risk of developing serious complications from flu such as hospitalisation, pneumonia, heart attack or death,"*

  The Committee found by unanimous decision that claim 2 was in breach of Section 13.4.1 of the Code.

- Claim 3: *"We don't want to see a group that has an increased risk of developing influenza complications be denied fair access to this vaccine because it is not funded."*

  The Committee found by unanimous decision that claim 3 was in breach of Section 13.4.1 of the Code.

Code Committee Sanctions
The Code Committee determined by unanimous decision that the breaches were moderate as defined in the Code of Conduct.

The Code Committee unanimously determined that the following sanctions should be imposed:
- The claims found in breach must not be used again in the same or similar form in a communication to the consumer media;
- A fine of $100,000 should be imposed.

Appeal
Sanofi Pasteur appealed against the decision of the Code Committee. Sanofi Pasteur argued that the claims found in breach were evaluated by the Code Committee as stand alone statements and not interpreted in the context of the press release.

The three claims were qualified appropriately in the media release, before and after each claim. In addition, Sanofi Pasteur argued that the media release contained no comparisons, either direct or otherwise, to any other influenza vaccine. The Code Committee had determined that the statements were implied comparisons between Fluzone® High-Dose and Fluad®. Sanofi Pasteur considered this is a result of interpreting the claims out of the context of the entire piece and evaluating them as stand-alone statements.

Sanofi Pasteur also stated that regarding the individual claims, a number of key points in its initial response to the complaint were not adequately taken into account by the Code Committee.

Response to the Appeal
Seqirus responded to the appeal, stating that the basis for the Code Committee's decision was that the media release was promotional and may have encouraged older Australians to seek a prescription for Fluzone High Dose. Whilst the claims may have been qualified in the media release, this does not alter the finding that the claims were promotional.

Seqirus rejected the arguments that the claims were considered in isolation rather than as part of the whole media release. Seqirus argued that it would not have made any difference in the Code Committee's consideration of the complaint if the claims were considered separately or as part of the whole media release.

In relation to Sanofi Pasteur's argument that the Code Committee did not adequately consider some of its key points in its response to the complaint, Seqirus responded that these arguments were not relevant to the complaint. Even if there were data to support the claims, they were promotional which is contrary to the Code.

Seqirus concluded that Sanofi Pasteur had not presented any arguments in its appeal that showed that the Code Committee had erred in its decisions. Seqirus argued that the appeal should be rejected and the finding of a moderate breach of Section 13.4.1 should be confirmed.

Appeals Committee Decision

- Claim 1: "Fluzone High-Dose has been clinically proven to protect against influenza and its complications such as hospitalisation among older adults,"

  The appeal by Sanofi Pasteur against the findings of the Code of Conduct Committee was not upheld. The Appeals Committee confirmed by majority decision that the claim was in breach of Section 13.4.1 of the Code.

- Claim 2: "We believe this is bad news for the older population who are at higher risk of developing serious complications from flu such as hospitalisation, pneumonia, heart attack or death,"

  The appeal by Sanofi Pasteur against the findings of the Code of Conduct Committee was not upheld. The Appeals Committee confirmed by unanimous decision that the claim was in breach of Section 13.4.1 of the Code.

- Claim 3: "We don't want to see a group that has an increased risk of developing influenza complications be denied fair access to this vaccine because it is not funded."

  The appeal by Sanofi Pasteur against the findings of the Code of Conduct Committee was not upheld. The Appeals Committee confirmed by unanimous decision that the claim was in breach of Section 13.4.1 of the Code.

Appeals Committee Sanctions

The Appeals Committee determined that the sanctions imposed by the Code of Conduct Committee should remain unchanged; that is the Appeals Committee confirmed:

- The claims found in breach must not be used again in the same or similar form in a communication to the consumer media;
- A fine of $100,000 should be imposed.

The Appeals Committee determined that the appeal bond of $20,000 should be retained by Medicines Australia.

Consideration of the Complaint

A member of the Code Committee provided some background on the supply of influenza vaccines funded by the Commonwealth Government under the National Immunisation program (NIP). The

choice of which brand of funded influenza vaccine is administered to a consumer is determined through the Commonwealth government procurement processes. If a vaccine is not included on the NIP, it may be prescribed by private prescription in which case the consumer and prescriber may choose which brand of vaccine is received. The Code Committee noted that for people aged 65 years and over, there are two 'improved' TGA-approved influenza vaccines for use in this age group which of equivalent effectiveness (Fluzone High-Dose and Fluad). However, only one of these two vaccines (Fluad) had been included on the NIP for people aged 65 years and over for the 2019 influenza vaccination program.

The media release issued by Sanofi Pasteur on 7 March 2019, directed to the consumer media, stated that Sanofi's Fluzone High-Dose influenza vaccine will not be funded through the NIP in 2019. It had been funded through the NIP in 2018. The media release included information on the influenza disease burden, hospitalisations and deaths, particularly in people aged over 65 years in 2017.

The complaint had identified three claims in the media release. The second claim was a statement from the Sanofi Pasteur General Manager, "We believe this is bad news for the older population who are at higher risk of developing serious complications from flu such as hospitalisation, pneumonia, heart attack or death,". The media release states that Fluzone High-Dose will be available on private prescription.

The Code Committee noted that the Code allows companies to issue a product specific consumer media statement, that is not promotional, to inform about a new or changed NIP listing. The Code Committee referred to the definition of "promotional" in the Code of Conduct glossary. Promotional statements include reference to the positive attributes of a product, statements about efficacy and comparative information.

A majority of the Code Committee considered that claim 1 was promotional because it claimed "clinically proven to protect against influenza and its complications such as hospitalisations". Whilst Fluzone High-Dose is approved for the active immunisation against influenza, there is no evidence in the PI supporting that Fluzone High-Dose is "clinically proven to protect against influenza" as this goes beyond a simple statement of the therapeutic indication. The effectiveness of Fluzone High-Dose vaccine has been established on the basis of non-inferior immune responses to the 3 strains in the vaccine against pre-set serological endpoints. There is no evidence presented in the PI that Fluzone High-Dose "protects against influenza" that is, the clinical manifestations of the disease. In addition, the statement referring to protecting against complications such as hospitalisations, there is no evidence in the PI to support this. Even if there were data to support this statement, a majority of the Code Committee considered that it is a promotional claim for the product and, as such, is not permitted in media releases to the general media.

One member of the Code Committee did not agree that claim 1 was promotional of a particular prescription medicine. The member considered that the statement was encouraging consumers to be immunised against influenza.

The Code Committee considered that claim 2, "We believe this is bad news for the older population who are at higher risk of developing serious complications from flu such as hospitalisation, pneumonia, heart attack or death", was inaccurate and misleading because it implies that older people will not have access to an influenza vaccine suitable for people 65 years

and over because Fluzone High-Dose was not included on the NIP, whereas another vaccine, Fluad, is still available on the NIP for older consumers. The Code Committee considered that the media release made an implied comparison between Fluzone High-Dose and Fluad. Whilst not identifying the alternative, funded vaccine, the media release implied that the alternative would not be as effective as Fluzone High-Dose, which was "bad news" for older people. The Code Committee considered that the media release was intended to encourage consumers to ask for the "high dose" influenza vaccine, rather than the "standard dose" vaccine that is funded through the NIP, because they would be at higher risk of complications from the flu. The media release would encourage consumers to seek a prescription for a specific prescription medicine, Fluzone High-Dose.

The Code Committee considered that claim 3, "We don't want to see a group that has an increased risk of developing influenza complications be denied fair access to this vaccine because it is not funded", was also promotional and encouraged consumers to seek a prescription for a particular prescription medicine, Fluzone High-Dose. This claim was also comparative with the alternative influenza vaccine. The Code Committee considered that this claim was also promotional because it encouraged consumers to believe that they might not be protected from influenza if they did not get access to Fluzone High-Dose.

The Code Committee determined by a majority decision that claim 1 was in breach of Section 13.4.1 of the Code. The Code Committee determined by unanimous decisions that claims 2 and 3 were in breach of Section 13.4.1 of the Code.

Sanctions

The Code Committee discussed the level of these breaches. It considered that the media release may have an effect on how the profession will prescribe the product but had no safety implications for patients. The Code Committee was concerned that the media release had the potential to cause concern and confusion amongst consumers about the vaccine that is currently available through the NIP and may encourage them to seek to be prescribed or administered Fluzone High-Dose privately. The Committee determined by unanimous decision that the breaches were moderate as defined in the Code of Conduct.

The Code of Conduct Committee unanimously determined that the following sanctions should be imposed:

- The claims found in breach must not be used again in the same or similar form in a communication to the consumer media;
- A fine of $100,000 should be imposed.

Consideration of the Appeal

The Chair explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code of Conduct Committee (Code Committee) involved an error on the basis of which the decisions of the Code Committee should be set aside or varied.

The Chair invited Sanofi Pasteur to give their appeal presentation. The following summarises that presentation and discussion with the Appeals Committee.

- Sanofi Pasteur explained its rationale for issuing the media release. In 2018, 1.6m older Australians had received Fluzone High-Dose but in 2019 Fluzone High-Dose was not funded by the Government under the National Immunisation Program (NIP). This had not been formally

announced and caused confusion for HCPs and patients. The media release was intended to avoid this confusion.

- The foundations of a successful immunisation program, which is a public program, are access; affordability; awareness – education of the community regarding the need for vaccination; acceptance – to reinforce the benefits of vaccination; and activation – to engage with the community and HCPs about getting vaccinated.
- The purpose of influenza vaccination is avoiding the risks of complications – respiratory, cardiovascular, hospitalisation and deaths.
- At no time in the media release was there a comparison with Seqirus' influenza vaccine. If such comparison had been included, the media would have pursued this aspect. However, Seqirus had cited only two media stories that were comparative, out of more than 600 media stories.
- The Code Committee's decisions were based on incorrect interpretation of the media release. Sanofi Pasteur consider that the statements in the media release subject to complaint are not promotional in the context of a public immunisation campaign. People over 65 years of age are at high risk of flu complications.
- In relation to claim 1, Sanofi Pasteur consider this to be a recitation of the indications for Fluzone High-Dose in lay language. If the language of the PI were used, it would not be understood by consumers; and they would not understand that the purpose of vaccination is to protect them from complications.
- Sanofi Pasteur noted that a member of the Code Committee had thought that the efficacy of Fluzone HD was based on immunogenicity, but there is information in PI from double blind trials of influenza protection. Therefore, the Code Committee had erred in stating that there was no evidence that Fluzone protects against influenza disease and therefore in its interpretation of claim 1. Claim 1 is a statement of the approved indications in lay language.
- In relation to claim 2, the reference to "bad news" relates to affordability, because patients would now have to pay for Fluzone High-Dose rather than receive it under the NIP. It also relates to access, because in 2018 patients had a choice of vaccines whereas in 2019 there was only 1 vaccine available under the NIP. The "bad news" is that patients would have to pay for a vaccine that was previously free.
- In answer to a question from the Appeals Committee about whether Sanofi Pasteur was arguing that there was less access to influenza vaccine for older people in general, Sanofi Pasteur responded that it was communicating that there was less choice for doctors and for patients. The media release states that there is a product funded through the NIP for people aged 65 and over. The access issue is about lack of choice.
- The reference in claim 2 to "higher risk of developing serious complications" is not an implied comparison with Fluad; it is a comparison with the population who are not receiving flu vaccination and who are at risk of complications from influenza. Sanofi Pasteur argued that this is not a comparison between the vaccines that people may or may not receive.
- The Sanofi Pasteur representatives concluded their presentation stating that the media release was not in breach of Section 13.4.1 of the Code.
- An Appeals Committee member noted that the ATAGI Guidelines state that both products are effective and there is no preference for one or the other. Sanofi confirmed that Fluzone High-Dose is high dose and Fluad is a standard dose with an adjuvant, but are both effective vaccines for influenza for people aged 65 years and over. An Appeals Committee member noted, and Sanofi Pasteur accepted, that a member of the public would not understand the term 'adjuvant' vaccine.

The Chairman thanked the Sanofi Pasteur representatives for their presentation and invited the Seqirus representatives to make their presentation to the Appeals Committee. The following summarises that presentation and discussion with the Appeals Committee.

- Seqirus confirmed that in 2018 both Fluzone High-Dose and Fluad were available on the NIP for adults aged 65 years and older. In 2019, only Fluad was available on the NIP because Seqirus had reached agreement with the Commonwealth and were asked to supply all people over 65 years of age. Sanofi Pasteur had chosen not to supply Fluzone High-Dose through the NIP and had issued the media release.
- Seqirus argued that the purpose of the media release was more than to avoid confusion. Seqirus disagreed with Sanofi Pasteur's argument about choice between vaccines. Vaccination providers do not have a choice; they only administer what has been provided to them. Fluzone High-Dose can be promoted to HCPs in the private prescription market.
- Both Fluad and Fluzone High-Dose can be used in people over 65 years of age; both are equivalent, with no clinical preference, but only Fluad was available under the NIP.
- Seqirus stated that the media release was promoting Fluzone High-Dose to the general public. The three claims were promotional and were comparative.
- Sanofi Pasteur had argued that the Code Committee had looked at the claims in isolation, but the entire media release was about Fluzone High-Dose not being funded on the NIP in 2019.
- By the use of "clinically proven" in claim 1, Sanofi Pasteur has gone further than just restating the approved indications by making an efficacy claim. In addition, Seqirus argued, there is no evidence that Fluzone High-Dose reduces hospitalisations. Seqirus reiterated that claim 1 was in breach of the Code.
- In relation to claim 2, Sanofi Pasteur had argued that the claim is not comparative and was merely stating that it was "bad news" that Fluzone High-Dose was not funded on the NIP. Seqirus argued that whilst there was no direct comparison with Fluad, the claim implies that the two vaccines are not equivalent and the lack of availability of Fluzone High-Dose was therefore "bad news" for patients. Seqirus had provided two transcripts from ABC news reports to illustrate that it wasn't only Seqirus that had found the media release was comparative. It would not have made any difference if the Code Committee had reviewed the claims in isolation or in the context of the whole media release.
- Sanofi Pasteur had argued that the Code Committee had not considered its arguments. Seqirus agree that all claims should be accurate, but they must not be promotional when included in a media release to the general public.
- Seqirus did not agree that the Code Committee had erred in its consideration of the complaint.

In response to a question from the Appeals Committee, Sanofi Pasteur agreed that both vaccines are effective in preventing influenza in the people aged 65 years and over.

In response to a further question, Sanofi Pasteur agreed that usually in any year patients don't get a choice as to which vaccine they will receive if they are both funded under the NIP. However, Sanofi Pasteur noted that in 2018 in WA doctors were able to order the vaccine they wanted. In 2019, many people showed a preference for Fluzone HD based on the evidence that they were willing to pay for it on a private prescription. The Appeals Committee member noted that therefore patients were not denied a choice. Sanofi Pasteur responded that patients should always have a choice and a choice between products provides security of availability in the market. Sanofi Pasteur considered that availability and preference are two different issues. An individual may have a preference of product, but how the product is supplied is not relevant to preference.

Sanofi Pasteur argued that Seqirus had misrepresented the statement from ATAGI in relation to there being no preference for either product. Sanofi Pasteur argued that HCPs need to understand the availability of products and be able to choose which product to administer. From the perspective of the NIP, there is no preference of product, but that is not necessarily indicative of individual preference. Sanofi Pasteur argued that the ATAGI assessment of the two products was in relation to a population group that is inherently at risk.

Sanofi Pasteur reiterated that it considered that claim 1 was a lay-language interpretation of the approved indications but accepted that the term 'adjuvant' is not lay language.

In response to a question from the Appeals Committee that the term "higher risk" could be misinterpreted as being due to the availability of Fluad and not Fluzone High-Dose on the NIP, Sanofi Pasteur responded that such an interpretation was not based on the evidence. The referenced ABC radio interview was an individual opinion about what the interviewed GP would choose for himself. The general public and lay media did not interpret the media release in that way. Sanofi Pasteur referred to 600 media stories that were positive about the need to get vaccinated.

A member of the Appeals Committee questioned Sanofi Pasteur about a media story that urged people to get the "high dose" vaccine that is thought to be more effective. Sanofi Pasteur responded that the media release had referred to both vaccines – one is higher dose and one is standard dose that contains an adjuvant. The media release stated that the adjuvanted vaccine remains NIP-funded. Sanofi Pasteur has tried to state that there are two vaccines that work differently but are both for influenza immunisation.

An Appeals Committee member questioned Sanofi Pasteur about its statement that a large number of people had expressed a preference for Fluzone High-Dose. Sanofi Pasteur responded the preference was by GPs. It had undertaken GP education about their product and about 10,000 people chose to receive Fluzone High-Dose.

An Appeals Committee member questioned the availability of Fluad via pharmacy administration. Seqirus responded that it only supplied the vaccine through the NIP and not the private market. In two states – WA and Victoria – pharmacists could administer the vaccine under the NIP, but in other states Fluad was not available for pharmacists to administer.

Appeals Committee members questioned Sanofi Pasteur about whether it agreed that the media release risked putting the NIP in disrepute because it implies that a poor decision was made in not funding Fluzone High-Dose. The member asked would this kind of message encourage 10,000 people to choose to pay for the vaccine and add to concerns that people have about influenza vaccination. Sanofi Pasteur responded that in 2019 there has been the highest number of people aged 65 and over (more than 90%) being immunised. If people had gone to see their GP about immunisation for influenza, this was of benefit to the NIP.

Sanofi Pasteur made its closing submissions. It reiterated that the media release was about supporting a public immunisation program. A record number of people are getting vaccinated. There are very few stories that support that the media release was promoting Fluzone High-Dose. It was only a call to action to get immunised, so as to prevent the complications of the flu for older people. There was no disparaging statement about Fluad in the media release. There was no

specific comparative statement in the media release. The focus of the release was on individual preferences; there was no intention to compare efficacy of the two products.

In response to a question from the Appeals Committee, Sanofi Pasteur stated that there is clinical evidence that immunisation prevents hospitalisations. In relation to timing of the increase in immunisation and publication of the media release, Fluzone High-Dose was available from late March 2019. The media release was issued on 7 March 2019. Sanofi Pasteur had started promoting Fluzone High-Dose to HCPs prior to publishing the media release. The NIP for 2019 began before both products were available. The two products have both been available during the flu season.

Seqirus made its closing remarks in response to the appeal. It stated that there had been no errors by the Code Committee in its reasons for decision. Sanofi Pasteur has presented no new evidence to demonstrate that the Code Committee had erred.

This concluded the company presentations and both parties were then excused from the hearing to allow the Appeals Committee to deliberate on the appeal.

The Appeals Committee discussed Sanofi Pasteur's appeal and Seqirus' response to the appeal and whether Sanofi Pasteur had presented any persuasive argument that the Code Committee had made an error in its decisions.

The Appeals Committee referred to the definition of promotion in the Code of Conduct Glossary, which describes promotion as a statement that "conveys the positive attributes of a product which extend beyond a simple non qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information."

In relation to claim 1, the Appeals Committee agreed with the Code Committee that there was no evidence in the PI that supported that Fluzone HD prevented hospitalisations. There may be other clinical evidence that shows that hospitalisation may be prevented by influenza vaccination. A majority of the Appeals Committee considered that Claim 1, which includes the statement "clinically proven to protect against influenza and its complications such as hospitalisations", was an efficacy claim and therefore was promoting the product.

A majority of the Appeals Committee did not accept Sanofi Pasteur's argument that claim 1 was merely a lay-language description of the approved indication. The Appeals Committee referred to the Fluzone High-Dose PI and noted that there was no reference in the indications to "clinically proven to protect against influenza". In addition, the PI states that, as with any vaccine, vaccination may not protect 100% of recipients. Further, the claim goes beyond the PI in its reference to protecting against complications such as hospitalisations. A majority of the Appeals Committee considered that the claim met the definition of promotion.

One Appeals Committee member was not persuaded that claim 1 was promotional. The member considered that the media release was informing the public that Fluzone HD was not funded in 2019. The member considered that the media release was not comparative because it did not mention any other product.

In a majority decision the Appeals Committee confirmed the decision of the Code Committee that claim 1 was promotional and was in breach of Section 13.4.1 of the Code.

In relation to claims 2 and 3, the Appeals Committee considered that the claims, which included the terms “bad news” and “denied fair access”, were highly emotive and went beyond simply educating the public about encouraging older Australian’s to be vaccinated and was promotional. The Appeals Committee referred to the ATAGI statement, which stated that “two higher-immunogenicity trivalent influenza vaccine (TIV) formulations (one ‘high-dose’ vaccine and another containing an adjuvant)” were available, which is more neutral and simply stated that an equivalent product was available on the NIP. The Appeals Committee considered that the media release was not balanced and contained promotional claims for Fluzone High-Dose.

The Appeals Committee considered that Sanofi Pasteur had not presented any reason that the Code Committee had erred in finding claims 2 and 3 in breach of the Code. The Appeals Committee agreed that the media release made an implied comparison between Fluzone High-Dose and Fluad. The Committee also agreed that the media release implied that the alternative product, which a group of Australians had been “denied fair access” to, would not be as effective as Fluzone High-Dose, which was therefore “bad news” for older people.

The Appeals Committee determined that the Code Committee’s reasons for finding the media release in breach of Section 13.4.1 of the Code were appropriate and had not involved any error in reaching its decisions.

The Appeals Committee confirmed by a majority decision that Claim 1 was in breach of Section 13.4.1 of the Code and that the appeal by Sanofi Pasteur should not be upheld.

The Appeals Committee unanimously confirmed the Code Committee’s decisions that Claims 2 and 3 were in breach of Section 13.4.1 of the Code and that the appeal by Sanofi Pasteur should not be upheld.

The Appeals Committee discussed the sanctions imposed by the Code Committee. It agreed that the breaches were moderate, as evaluated by the Code Committee. The Appeals Committee unanimously determined that the fine of $100,000 imposed by the Code Committee should not be varied.

The Appeals Committee unanimously agreed that as the appeal had not been upheld, the $20,000 bond paid by Sanofi Pasteur should be retained by Medicines Australia.