COMPLAINT NUMBER	17/333
AWAP	17/001
COMPLAINANT	AFT Pharmaceuticals
ADVERTISER	Reckitt Benckiser
ADVERTISEMENT	Nuromol, In-store Poster
DATE OF MEETING	13 October 2017
OUTCOME	Settled, in part; Upheld, in part

SUMMARY

The two page product detailer advertisement for Nuromol included the Nuromol logo and a picture of the product packaging. The front of the advertisement said, in part: **"WHY NUROMOL IS THE BETTER CHOICE"** and included the claims: "Improved patient compliance" and "More ibuprofen per dose than Maxigesic." The reverse side of the advertisement should a table titled: "Nuromol vs. Maxigesic **WHAT IS THE DIFFERENCE?** and included the claims "Dosage per day: Nuromol – 3 times Maxigesic – 4 times" and "Accepted dosage of Paracetamol to cause toxicity (10g): Nuromol – 3.3 times / Maxigesic – 2.5 times".

The Complainant raised concerns about the placement of the advertisement, a product detailer intended for healthcare professionals such as Pharmacists, in a Pharmacy where consumers could see it. The Advertiser said the product detailer was intended for Pharmacists as a leave behind only, not consumer display and requested the complaint be Settled as it had acted to remove the advertisement and undertook not to use it again.

The Complainant acknowledged the advertisement was not deliberately intended for public display, and accepted that the advertisement was removed from consumer view.

The Panel noted the self-regulatory actions of the Advertiser and Pharmacy to immediately remove the advertisement from consumer display and their undertaking to review their processes surrounding the placement of advertisements in-store. The Panel ruled the placement of the advertisement was Settled.

The Complainant was still concerned about four specific claims made in the product detailer advertisement which it said were misleading and were unable to be substantiated.

The majority ruled that no substantiation was provided to support the claim that Nuromol had "Improved Patience Compliance" and due to the ambiguity of the claims and lack of evidence, it was likely to mislead and was therefore in breach of Principle 2 and Rule 2(a) or Rule 2(c) Therapeutic and Health Advertising Code.

A minority disagreed and said the target audience were more informed than would be the case if the advertisement were for public display and taking into account the information contained in the advertisement it did not reach the threshold to be considered misleading.

The Panel said the claims Nuromol had more ibuprofen than Maxigesic and that Nuromol only required three doses a day versus four doses for Maxigesic were factual statements and taking into account the target audience of the advertisement and the information contained in the advertisement, ruled they were unlikely to mislead. The Panel said the claims were not in breach of Principle 2 of the Therapeutic and Health Advertising Code.

The majority of the Panel said the claim that Maxigesic contained more Paracetamol and therefore only took 2.5 times the maximum recommended daily of Paracetamol to cause toxicity was misleading by way of exaggeration and, without justifiable reason, played on fear. It said the accidental or intentional misuse of medicines as support for the claim to promote the benefits of one product over another was irresponsible and misleading, even in the context of an advertisement directed to healthcare professionals. The majority said the information contained in the advertisement did not support the implied claim that Maxigesic was more likely to cause toxicity than Nuromol and it ruled the claim was misleading, in breach of Principle 2 of the Therapeutic and Health Advertising Code.

A minority disagreed. It said the claim was factual in so far as Maxigesic contains more Paracetamol (4000mg) than Nuromol (3000mg) per maximum recommended daily dose and noted those figures were clearly presented in the advertisement. The information that it only takes 2.5 times the maximum daily dosage of Maxigesic to cause Paracetamol toxicity compared to 3.3 times the maximum daily dosage of Nuromol was also factual. Taking into account the intended informed audience of the advertisement, the minority said the claim did not reach the threshold to be considered misleading and was not in breach of Principle 2 and Therapeutic and Health Advertising Code.

In accordance with the majority, the Panel ruled the complaint was Settled, in part and Upheld, in part.

[Advertisement withdrawn]

Please note this headnote does not form part of the Decision.

PROCEDURE

The Chair ruled to deal with the matter by “adjudication with attendance of the parties” pursuant to Rule 3 of the Complaints Procedures of the Advertising Standards Complaints Board. This system is designed to resolve disputes between competitors, and a Panel was appointed.

THE PANEL

Chair – R. Anderson, Chair of the Advertising Standards Complaints Board.
Co-panelists – C. Magee (Alternate Public Member of the Advertising Standards Complaints Board) and N. Keats (Alternate Industry Member of the Advertising Standards Complaints Appeals Board).

THE PARTIES

The Complainant, AFT Pharmaceuticals (AFT): Written submissions by Hartley Atkinson, Managing Director. Oral submissions presented by Murray Keith, Marketing Manager and Vladimir Ilievski, Regulatory Affairs Manager.

The Advertiser, Reckitt Benkiser (RB): Written submissions by Janie Heywood, Director Regulatory and Medical Affairs. Oral submissions were presented via telephone by Janie Heywood and Angela Lin, Legal Director

PANEL DECISION

The Chair directed the Panel to consider the advertisements with reference to Principle 2 and Rule 2(a) and Rule 2(c) of the Therapeutic and Health Advertising Code.

Principle 2 of the Therapeutic and Health Advertising Code required the Complaints Board to consider whether the advertisement was truthful, balanced and not misleading. Advertisements shall not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole. Rule 2(a) of the same Code require advertisements were accurate and that statements and claims are valid and able to be substantiated. Substantiation should exist prior to a claim being made. For medicines and medical devices, therapeutic claims must be consistent with the approved indication(s) (for medicines) or the listed intended purpose (for medical devices).

Rule 2(c) of the same Code required comparative advertising be balanced and not misleading, or likely to mislead, either about the product, device or service advertised or classes of products, devices or services, with which the comparison is made. Comparative advertisements shall not be disparaging and shall be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence.

> i. Comparative advertisements should not discourage consumers from following the advice of their healthcare practitioner.
>
> ii. Comparative advertisements should compare 'like with like'. Advertisements for Natural Health Products and Dietary Supplements shall not include comparisons with medicines or medical devices either specifically or generally.

The Advertisement

The Panel confirmed the advertisement before it was a product detailer for Nuromol, intended to provide information to healthcare professionals such as Pharmacists. It took into account the definition of an advertisement:

> “Advertising and advertisement(s)” are any message, the content of which is controlled directly or indirectly by the advertiser, expressed in any language and communicated in any medium with the intent to influence the choice, opinion or behaviour of those to whom it is addressed.”

It confirmed that the content before it met the definition of an advertisement for the purposes of the Advertising Codes of Practice and noted jurisdiction was not disputed by either party.

The Panel made several observations about the advertisement before it. It said the advertisement was a comparative advertisement as it employed many comparative claims with obvious comparative language such as: “Why Nuromol is the better the choice”, “stronger pain relief”, “longer lasting”, “improved patient compliance” and “more ibuprofen than Maxigesic”. The Panel also noted the comparative table used in the advertisement which listed various aspects of Nuromol compared to Maxigesic specifically.

Turning its attention to the comparative table, the Panel noted the column relating to Nuromol was primarily coloured green and the column relating to Maxigesic was primarily red where the “Paracetamol per tablet” and “Maximum Ibuprofen per day dose” were grey. The exception was the row titled “Codeine Free” which was green for both products and included a tick. The Panel said the composition of the table and the colours used created a strong impression that Nuromol was a superior product in most aspects.

Further, the Complaints Board noted the target audience for the advertisement was healthcare professionals such as Pharmacists. It acknowledged that others, outside the target audience, would also be likely to see the advertisement, for example, retail assistants who were not pharmacy trained. However, the Panel considered the environment in which the advertisement was intended to be seen, was more informed than one in which a general and untargeted audience would be likely to see it.

Complainant’s Submission

The Complainant raised concerns about the placement of the advertisement, a product detailer intended for healthcare professionals such as Pharmacists, in a Pharmacy where consumers could see it. However, the Complainant acknowledged the advertisement was not deliberately intended for public display, and accepted that the advertisement was removed from consumer view.

The Complainant was still concerned about four specific claims made in the product detailer advertisement. These follow:

“Improved Patient Compliance”: The Complainant said, in part: “When the word ‘improved' is used it implies a comparison is being made. There is no clear indication of what Nuromol's® patient compliance has been compared to. Through omission of a comparative product, we believe that this renders the statement unbalanced and misleading… There is no data or facts shown to support that there is improved patient compliance. Without any reference exhibited, we believe that this statement is also misleading.”

“More ibuprofen per dose than Maxigesic”: The Complainant said, in part: “this statement could be misleading to a pharmacist, pharmacy retail staff, and/or Medical Practitioner, as there is no explanation provided as to what constitutes a dose. An individual can take I or 2 tablets of Nuromol® (200mg ibuprofen) every 6 — 8 hours, whilst 1 or 2 tablets of Maxigesic® (150mg ibuprofen) can be taken every 4 — 6 hours. Per dose' could refer to 'daily dose', which would mean the same dosage (1200mg) of ibuprofen is provided (maximum daily ibuprofen dose) for both Nuromol and Maxigesic®, potentially rendering this statement misleading and inaccurate.”

“Dosage Per Day — Nuromol: 3 times and Maxigesic: 4 times”: The Complainant said, in part: “We believe that this statement is misleading as it is vague and omits key information such as: how many tablets this refers to and/or whether this is the maximum dosage frequency per day. The information provided in the table does not take into consideration that "Dosage per day" is variable and dependent on the individual.”

“Accepted dosage of Paracetamol to cause toxicity (10g)”: The Complainant said, in part: “We believe this claim is misleading as it implies it is 'easier' to reach the accepted dose of Paracetamol to cause toxicity via Maxigesic'. However, there is a maximum dosage per day of Maxigesic stated on the pack to ensure toxicity is not reached. This statement presented on the advertisement is irrelevant as an individual should be following the maximum dosage guidelines provided on the pack. There is a risk of toxicity for any individual who does not follow dosage guidelines for every medicine. Nowhere on the Maxigesic pack do we state to take more than the maximum dosage… in the case of overdose, tablets are ingested as opposed to ‘multiples of the daily maximum dose’ hence the number of tablets is the key parameter and in this respect, the comparison is misleading and we believe is in breach. In fact, it should be noted that a patient ingesting multiple tablets of Nuromol' would receive a greater amount of total active ingredients placing them at greater risk of toxicity, as toxicity is not solely attributable to the Paracetamol.”

Advertiser’s Submission

The Advertiser said the product detailer was intended for Pharmacists as a leave behind only, not consumer display and requested the complaint be Settled as “the one use of the Nuromol Detailer in the Unichem Pharmacy had already been rectified and that this detailer has been superseded and given the material, which was the subject of AFT's complaint has not been used by RB for close to 6 months, RB responded to AFT's letter on 5th September, confirming that;

- The piece in question was not intended for public display.
- The material was only displayed in the UniChem Pharmacy in Ponsonby, inadvertently by the pharmacist, without RB's knowledge.
- RB has acted swiftly to ensure that the material was taken down and confirmed that the material was taken down.”

The Advertiser reiterated its view in oral submissions and provided some context about to the intention and nature of the claims made in the advertisement. Of relevance to the Panel’s discussion, the Advertiser said, in summary:

Improved Patient Compliance referred to the frequency of tablets required and that it was commonly understood by medical practitioners that where fewer doses are required to be taken there is improved patient compliance (meaning patients are more likely to take the correct daily dosage). It noted the fact that less doses per day of Nuromol were required than for Maxigesic and therefore would have better patient compliance.

Regarding the claims that Nuromol has *more Ibuprofen than Maxigesic* and requires less *Doses per day* the Advertiser said this information was factual as it related to ingredients and dosage of the products in comparison where the information to support the claims was clearly articulated in the advertisement.

In relation to the claim about the *Accepted dosage of Paracetamol to cause toxicity*, the Advertiser made a verbal undertaking that any similar comparative claims made in future would be clear and

factually correct to avoid any confusion. The Advertiser also said it would not use the Starship Health Guidelines on Paracetamol Poisoning to support any such claim in future as there were more appropriate references to support the dosage of Paracetamol to cause toxicity.

Panel Discussion

The Panel read all of the relevant correspondence regarding the present matter, viewed copies of the advertisements and noted the Complainant's concerns that the Advertiser made misleading claims in the comparative advertisement.

The Panel confirmed that its role was to consider the advertisement, and the claims made in it, from the perspective of their likely audience. It then had to consider whether the information provided to it, when taken at face value, went far enough to substantiate the claims made in the advertisement. It also noted that the onus fell on the Advertiser to substantiate the claims in the advertisement.

Placement

The Panel noted the concerns of the Complainant about the detailer advertisement being displayed to consumers in a Unichem Ponsonby Pharmacy on August 7th 2017, stating, in part: "We acknowledged that the material was not deliberately intended for public display, and accepted that the advertisement was removed from consumer view. Nonetheless, we had also submitted to them that we believed that the material was misleading when presented to Pharmacy staff [Pharmacists and Pharmacy Retail staff] and/or Medical Practitioners. Whether this advertisement is shown to consumers and/or people in healthcare professions, in our view the ASA Therapeutic and Health Advertising Code has been breached."

The Panel noted the response from the Advertiser where it said the advertisement "was not intended for public display; was only displayed in the UniChem Pharmacy in Ponsonby, inadvertently by the Pharmacist, without RB's knowledge; RB has acted swiftly to ensure that the material was taken down and confirmed that the material was taken down; RB considers this matter to be closed."

Green Cross Health, owner of the Unichem Pharmacy where the advertisement was displayed, responded to the complaint, saying, in part: "the promotional material provided by the manufacturer was displayed by 1 pharmacy and they did so on the belief that the manufacturer had met all the requirements around advertising standards. They removed the material immediately when advised by the manufacturer. We have sent a communication to all pharmacies outlining the code of ethics that should be followed at all times around advertising in line with Pharmacy Council of New Zealand and that all material received Our Merchandising Team have been advised in writing that in future when working with suppliers that they are asked to confirm that all promotional and educational material used has TAPS approval prior to being distributed to pharmacies and that no material should be available without the appropriate TAPS approval."

The Panel considered the placement of the advertisement in a Pharmacy. It noted the responses from both the Advertiser and the Green Cross Health relating to the error and remedial self-regulatory action taken to remove the advertisement from display to consumers. It took into account that consumers were not the intended audience and the advertisement had been incorrectly placed as part of a display in one Pharmacy.

Noting the self-regulatory actions of the Advertiser and Pharmacy to immediately remove the advertisement from consumer display and their undertaking to review their processes surrounding the placement of advertisements in-store, the Panel ruled the placement of the advertisement was Settled and it was to consider the advertisement from the perspective of its intended audience.

The Panel noted the Complainant accepted the advertisement was displayed as an in-store poster in error but was still concerned it contained misleading information for the intended audience.

Claim 1: "Improved Patience Compliance"

The Panel noted the claim "Improved Patience Compliance" appeared on the front of the advertisement and was number three in a list of four "Reasons to recommend Nuromol".

It noted the Complainant's concern the claim was misleading because the basis of comparison was not clear and there was no substantiation to support that Nuromol had a better compliance rate than other products, or Maxigesic specifically.

The Advertiser said the claim referred to the fact that Nuromol requires less doses per day to reach the maximum dosage and therefore, people were more likely to comply with taking the recommended daily dose. The Advertiser acknowledged the claim could be ambiguous and said it would make any similar claims clearer in any future advertising.

The majority of the Panel confirmed "Improved Patience Compliance" was a comparative claim as it denoted that people are more likely to take the recommended daily dosage of Nuromol when compared with other products. The majority confirmed the claim was open to interpretation and the basis of the comparison was unclear, even when considered in the context of an advertisement directed at an informed audience. The majority said there was no evidence provided to support that Nuromol had "improved patient compliance", or that taking less doses in a 24-hour period improved patient compliance.

The majority of the Panel noted that Principle 2 and Rules 2(a) and 2(c) of the Therapeutic and Health Advertising Code required that advertisements are accurate and statements and claims are valid and able to be substantiated, comparative advertisements are required not to be disparaging and should be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence. Taking into account that no substantiation was provided to support the claim and noting the level of ambiguity the majority said it was likely to mislead and was therefore in breach of Principle 2 and Rules 2(a) and 2(c) of the Therapeutic and Health Advertising Code.

A minority disagreed. It said the advertisement was directed at healthcare professionals such as Pharmacists who were a more informed audience than would be the case if the advertisement were for public display and the reverse side of the advertisement made clear that Nuromol required fewer doses per day than Maxigesic. The minority accepted that while it could have been clearer as to the basis of the claim, it did not reach the threshold to be considered misleading to the audience to whom it was directed. The minority said the claim did not reach the threshold required to breach Principle 2 and Rule 2(c) Therapeutic and Health Advertising Code.

In accordance with the majority, however, the Panel ruled the complaint relating to the claim "Improved Patient Compliance, was Upheld.

Claim 2: "More Ibuprofen than Maxigesic"

The Panel noted the claim "More Ibuprofen than Maxigesic" appeared on the front of the advertisement as the last of four "Reasons to recommend Nuromol".

It noted the Complainant's concern the claim was misleading because it was not clear in the advertisement what constituted a dose in relation to the claim, whether it was single dose or daily dosage.

The Advertiser said it was clear in the advertisement that Nuromol contains 200mg of ibuprofen per tablet versus 150mg of ibuprofen in Maxigesic.

The Panel considered the claim that Nuromol had more ibuprofen than Maxigesic was a factual statement and information provided in the advertisement, both on the Nuromol packaging shown on the front of the detailer and in the table on the reverse, supported the statement. The Panel said, taking into account the target audience of the advertisement, the claim that Nuromol has more Ibuprofen than Maxigesic obviously referred to the per tablet dose and was unlikely to mislead the audience to whom it was directed. The Panel said the claim was not in breach of Principle 2 of the Therapeutic and Health Advertising Code.

Accordingly, the Panel ruled the complaint relating to the claim "More Ibuprofen than Maxigesic", was Not Upheld.

Claim 3: "Dosage per day: Nuromol – 3 times / Maxigesic – 4 times"

The Panel noted the claim "Dosage per day: Nuromol – 3 times / Maxigesic – 4 times" appeared on the back of the advertisement as part of a comparative table titled "Nuromol vs. Maxigesic what is the difference?"

The Complainant said the statement was vague and omitted key information and did not take into account that dosage is variable depending on the individual.

The Advertiser said the claim was based on factual information that Nuromol only required three doses a day versus four doses for Maxigesic.

The Panel said the claim that Nuromol only required three doses a day versus four doses for Maxigesic was a factual statement and taking into account the target audience of the advertisement, it was unlikely to mislead. The Panel said the claim was not in breach of Principle 2 of the Therapeutic and health Advertising Code.

Accordingly, the Panel ruled the complaint relating to the claim "Dosage per day: Nuromol – 3 times / Maxigesic – 4 times" was Not Upheld.

Claim 4: "Accepted dosage of Paracetamol to cause toxicity (10g): Nuromol – 3.3 times / Maxigesic – 2.5 times"

The Panel noted the claim “Accepted dosage of Paracetamol to cause toxicity (10g)” appeared on the back of the advertisement as part of a comparative table titled “Nuromol vs. Maxigesic what is the difference?”

The Complainant said the claim was misleading as it implied it was ‘easier’ to reach the maximum dose of Paracetamol to cause toxicity taking Maxigesic when the recommended dose was clearly on the pack and there was a risk for anyone who did not follow the dosage guidelines.

The Advertiser said that 10mg was the accepted dosage of Paracetamol to cause toxicity, however, it accepted the reference used in the advertisement was not wholly appropriate to support this. The Panel noted the Advertiser’s verbal undertaking that it would not use a claim relating to toxicity in future advertising without robust evidence and clarification to avoid confusion. The Complainant agreed that 10mg was the accepted dosage of Paracetamol to cause toxicity.

The majority of the Panel said the claim about toxicity was misleading by way of exaggeration and, without justifiable reason, played on fear. It noted the source of the claim was referenced in the advertisement was ‘Paracetamol Poisoning’ in the Starship Children’s Health Guidelines which related to “poisonous ingestions in young children” and “intentional self-harm in teenagers”. The majority said using a source that related to the accidental or intentional misuse of medicines as support for the claim to promote the benefits of a product over another was irresponsible and misleading, even in the context of an advertisement directed to healthcare professionals.

The majority noted the product was a general use pain reliever, which contained clear dosage instructions on the package and was only available through a pharmacy. It said the overall impression conveyed by the advertisement, including the reference to the Starship Children’s Health Guidelines, is that Maxigesic is more likely to cause Paracetamol toxicity than Nuromol which was not been substantiated. It said the claim was misleading, in breach of Principle 2 of the Therapeutic and Health Advertising Code.

A minority disagreed. It said the claim was factual in so far as Maxigesic contains more Paracetamol (4000mg) than Nuromol (3000mg) per maximum recommended daily dose. It is also factual that it takes 2.5 times the maximum daily dosage of Maxigesic to cause Paracetamol toxicity compared to 3.3 times the maximum daily dosage of Nuromol. It noted those figures were clearly presented in the advertisement which was directed at healthcare professionals who were a more informed audience on these topics. The minority said the reference to the Starship Children’s Health Guidelines did not cause the advertisement to be misleading by way of exaggeration because it did not affect the overall impression conveyed by the advertisement. It accepted the reference provided in the advertisement identified that 10mg of Paracetamol was the ‘accepted dosage to cause toxicity’ and that the Complainant agreed this was the dosage to cause toxicity.

The minority said said the reference did not convey the impression that Maxigesic was more likely to cause poisonous ingestions in young children or more likely to be used for intentional self-harm in teenagers. Therefore, the minority said the claim did not reach the threshold to be considered misleading and was not in breach of Principle 2 and Therapeutic and Health Advertising Code.

However, in accordance with the majority, the Panel ruled the complaint relating to the claim “Accepted dosage of Paracetamol to cause toxicity (10g): Nuromol – 3.3 times / Maxigesic – 2.5 times” was Upheld.

Summary

The Panel said the advertisement was a comparative advertisement as it employed many comparative claims with obvious comparative language and used a comparative table.

Placement: Settled

The Panel noted the self-regulatory actions of the Advertiser and Pharmacy to immediately remove the advertisement from consumer display and their undertaking to review their processes surrounding the placement of advertisements in-store. The Panel ruled the complaint about placement of the advertisement was Settled.

Claim 1: Upheld

The majority ruled that as no substantiation was provided to support the claim that Nuromol had "Improved Patience Compliance" and due to its ambiguity and lack evidence it was generally accepted, it was likely to mislead and was therefore in breach of Principle 2 and Rule 2(c) Therapeutic and Health Advertising Code.

Claims 2 and 3: Not Upheld

The Panel said the claims Nuromol had more ibuprofen than Maxigesic and that Nuromol only required three doses a day versus four doses for Maxigesic were factual statements and taking into account the target audience of the advertisement and the information contained in the advertisement, ruled they were unlikely to mislead. The Panel said the claims were not in breach of Principle 2 of the Therapeutic and Health Advertising Code and ruled the complaints relating to them were Not Upheld.

Claim 4: Upheld

The majority of the Panel said the claim that Maxigesic contained more Paracetamol and therefore only took 2.5 times the recommended dosage of Paracetamol to cause toxicity was misleading by way of exaggeration and, without justifiable reason, played on fear. It said the accidental or intentional misuse of medicines as support for the claim to promote the benefits of a product over another was irresponsible and misleading, even in the context of an advertisement directed to healthcare professionals. The majority said the information contained in the advertisement did not support the claim that Maxigesic was more likely to cause toxicity than Nuromol and it ruled the claim was misleading in breach of Principle 2 of the Therapeutic and Health Advertising Code and ruled the complaint about to the claim was Upheld.

The Panel therefore ruled the complaint was Settled, in part and Upheld, in part.

Decision: Complaint **Settled, in part, Upheld, in part**

DESCRIPTION OF ADVERTISEMENT

The two page product detailer advertisement for Nuromol included the Nuromol logo and a picture of the product packaging.

The front of the advertisement said, in part:

> **"WHY NUROMOL IS THE BETTER CHOICE**
>
> REASONS TO RECOMMENT NUROMOL
> 1. Stronger pain relief
> 2. Longer Lasting
> 3. Improved patient compliance
> 4. More ibuprofen per dose than Maxigesic."

The reverse side of the advertisement said, in part:

> "Take back what intense pain steals with STRONGER FOR LONGER PAIN RELIEF."

It included a graph titled "Mean pain relief and intensity differences shown at each time point (intention to treat population)" which compared the "Sum of the pain intensity" against the "time (hours) for 2 x ibuprofen 200mg/ paracetamol 500mg (NUROMOL) and 2 x paracetamol 500mg / codeine 15mg."

The advertisement also included a table titled: "Nuromol vs. Maxigesic **WHAT IS THE DIFFERENCE?**

	Nuromol	**Maxigesic**
Ibuprofen per tablet	200mg	150mg
Paracetamol per tablet	500mg	500mg
Dosage per day	3 times	4 times
Maximum Daily Dose	6 tablets	8 tablets
Maximum Ibuprofen per day dose	1200mg	1200mg
Maximum Paracetamol per day dose	3000mg	4000mg
Accepted dose of paracetamol to cause toxicity (10mg)	3.3 times	2.5 times
Codeine Free	✓	✓

COMPLAINT FROM AFT PHARMACETICALS

It came to our attention that a Nuromol double sided advertisement (see appendices 1 and 2) was displayed to consumers in Unichem 218 Ponsonby Pharmacy on August 7th 2017. We believed that the advertisement contained material that was not appropriate for consumers. Thus we outlined in a letter to Reckitt Benckiser the various instances in which we believed that the Advertising Standards Authority (ASA) Therapeutic and Health Advertising Code had been breached.

In response, Reckitt Benckiser stated that the advertisement was developed for Healthcare Professionals as an educational tool and that Reckitt Benckiser had asked the Pharmacy in question to take the poster down as a matter of urgency.

We acknowledged that the material was not deliberately intended for public display, and accepted that the advertisement was removed from consumer view. Nonetheless, we had also submitted to them that we believed that the material was misleading when presented to Pharmacy staff [Pharmacists and Pharmacy Retail staff] and/or Medical Practitioners. Whether this advertisement is shown to consumers and/or people in healthcare professions, in our view the ASA Therapeutic and Health Advertising Code has been breached.

Unfortunately, in response to two separate letters, Reckitt Benckiser completely disregarded our concerns relating to various breaches of the ASA Therapeutic and Health Advertising Code. Reckitt Benckiser claimed that they had no responsibility for the material being displayed, however did not address our view that the material remained misleading when presented to Healthcare Professionals, which we had clear14 outlined to them on two separate occasions. Given that Reckitt Benckiser considers this matter closed and does not intend to respond to other matters raised in our correspondence, we would like to lodge a complaint to the Advertising Standards Authority. This resolution avenue has been communicated to them in our ongoing correspondence.

Unfortunately there is some history between AFT and RB, and previously in Australia, RB refused to acknowledge our advertising concerns which resulted in AFT ultimately taking the complaint to an independent body which upheld the majority of our concerns [July 2015]. Hence in this case we have already indicated to RB that if we cannot resolve this issue, we will take this to the ASA. The concerns have not been resolved nor acknowledged which is the reason that we are now making the complaint.

Below we have outlined the various instances in which we believe the ASA Therapeutic and Health Advertising Code has been breached.

Appendix 1. Front Side of Advertisement:

We believe that the claim **"Improved Patient Compliance"** breaches Guideline 2 (c) of Principle 2: *"Comparative advertising shall be balanced and shall not be misleading or likely to be misleading, either about the product advertised or classes of products with which the comparison is made."* When the word Improved' is used it implies a comparison is being made. There is no clear indication of what Nuromol's® patient compliance has been compared to. Through omission of a comparative product, we believe that this renders the statement unbalanced and misleading.

In addition, we believe that the claim **"Improved Patient Compliance"** also breaches Guideline 2(a) of the ASA Therapeutic and Health Advertising Code Principle 2, *"Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated."* There is no data or facts shown to support that there is improved patient compliance. Without any reference exhibited, we believe that this statement is also misleading.

Furthermore, we believe the claim **"More ibuprofen per dose than Maxigesic™"**, also breaches Principle 2 of the ASA Therapeutic and Health Advertising Code: *"Advertisements shall be truthful, balanced and not misleading. Advertisements should not or should not be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity,*

exaggerated or unrealistic claim or hyperbole." This statement could be misleading to a pharmacist, pharmacy retail staff, and/or Medical Practitioner, as there is no explanation provided as to what constitutes a dose. An individual can take I or 2 tablets of Nuromol® (200mg ibuprofen) every 6 — 8 hours, whilst 1 or 2 tablets of Maxigesic® (150mg ibuprofen) can be taken every 4 — 6 hours. Per dose' could refer to 'daily dose', which would mean the same dosage (1200mg) of ibuprofen is provided (maximum daily ibuprofen dose) for both Nuromo0 and Maxigesie®, potentially rendering this statement misleading and inaccurate.

Appendix 2. Back Side of Advertisement:

"Dosage Per Day — Nuromol: 3 times and Maxigesic: 4 times" — in our view, this statement breaches Principle 2 of the ASA Therapeutic and Health Advertising Code: *"Advertisenrs shall be truthful, balanced and not misleading. Advertisements should not or should not be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole."* We believe that this statement is misleading as it is vague and omits key information such as: how many tablets this refers to and/or whether this is the maximum dosage frequency per day. The information provided in the table does not take into consideration that "Dosage per day" is variable and dependent on the individual.

In our view, the claim, **"Accepted dosage of Paracetamol to cause toxicity (10g)"**, also breaches Principle 2 of the ASA Therapeutic and Health Advertising Code: *"advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated"* Principle 2 also states, *"Advertisements shall be truthful, balanced and not misleading. Advertisements should not or should not be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole."* We believe this claim is misleading as it implies it is 'easier' to reach the accepted dose of Paracetamol to cause toxicity via Maxigesic'. However, there is a maximum dosage per day of Maxigesic stated on the pack to ensure toxicity is not reached. This statement presented on the advertisement is irrelevant as an individual should be following the maximum dosage guidelines provided on the pack. There is a risk of toxicity for any individual who does not follow dosage guidelines for every medicine. Nowhere on the Maxigesic pack do we state to take more than the maximum dosage.

Moreover, in the case of overdose, tablets are ingested as opposed to "multiples of the daily maximum dose" hence the number of tablets is the key parameter and in this respect, the comparison is misleading and we believe is in breach. In fact it should be noted that a patient ingesting multiple tablets of Nuromol' would receive a greater amount of total active ingredients placing them at greater risk of toxicity, as toxicity is not solely attributable to the Paracetamol component.

THE RELEVANT PROVISIONS OF THE CODE OF PRACTICE

THERAPEUTIC HEALTH AND ADVERTISING CODE

PRINCIPLE 2: TRUTHFUL PRESENTATION Advertisements shall be truthful, balanced and not misleading. Advertisements shall not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole.

Rule 2(a)

Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated. Substantiation should exist prior to a claim being made. For medicines and medical devices, therapeutic claims must be consistent with the approved indication(s) (for medicines) or the listed intended purpose (for medical devices).

Guidance Note: In addition to the ASA Guidance Note on Responding to a Complaint about Misleading Claims, the following guidance is specific to advertising therapeutic products, natural health products and dietary supplements and health services. Substantiation varies for claims made in advertisements depending on what is being advertised. For example;

i. Therapeutic claims for Medicines shall be those approved by Medsafe and thus would be consistent with the product Data Sheet, Consumer Medicine Information and / or the approved Label.

ii. Therapeutic claims for Medical Devices should be consistent with the 'Intended Purpose' noted on the WAND listing and the claims must be able to be supported by appropriate substantiation.

Medical Devices must be listed on WAND within 30 working days after the device is first imported, exported or manufactured (Note: There are some exceptions to this WAND listing requirement).

There is no independent evaluation in New Zealand of the substantiation for claims made about a medical device. The onus to have substantiation on-hand and provide it when necessary, lies with the advertiser.

Please note: The WAND database is not accessible to members of the public or any other party except Medsafe and the New Zealand sponsor.

Note: It is an offence under the Fair Trading Act to make a claim in an advertisement that cannot be substantiated. Advertisers must be able to back up a claim before the claim is made in an advertisement. This Commerce Commission Fact Sheet provides an overview of the substantiation provisions of the Fair Trading Act.

Rule 2(c)

Comparative advertising shall be balanced and shall not be misleading, or likely to be misleading, either about the product, device or service advertised or classes of products, devices or services, with which the comparison is made.

i. Comparative advertisements shall not be disparaging and shall be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence.

ii. Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner.

iii. Comparative advertisements shall compare 'like with like'. Advertisements for Natural Health Products and Dietary Supplements shall not include comparisons with medicines or medical devices either specifically or generally.

RESPONSE FROM ADVERTISER, RECKITT BENKISER

Reckitt Benckiser (RB) is in receipt of the complaint issued by AFT Pharmaceuticals and provides the following response.

AFT first raised its concern in relation to what it perceived to be a 'poster' advertising Nuromol to consumers in the UniChem Pharmacy in Ponsonby Auckland in a letter dated 23rd August 2017. RB responded to this correspondence by stating:

- The Nuromol piece was a detailer developed for healthcare professionals and was being used by the sales team;
- This Nuromol detailer was not intended to be left behind or used as a consumer promotional piece;
- The UniChem pharmacy displayed this Nuromol detailer without consulting RB and as such RB was not aware of this activity occurring; and
- RB has contacted the pharmacy and asked that the Nuromol detailer be taken down as a matter of urgency.

In its correspondence to RB on the 31st August 2017, AFT responded with the following points;

- AFT acknowledges that the RB promotional piece was not deliberately intended for public display; and
- Nonetheless whether it be directed to consumers or healthcare Professionals, AFT is of the view that the material is misleading raising some concerns with claims being communicated.

In light of the fact that the one use of the Nuromol Detailer in the UniChem pharmacy had already been rectified and that this detailer has been superseded and given the material, which was the subject of AFT's complaint has not been used by RB for close to 6 months, R8 responded to AFT's letter on 5th September, confirming that;

- The piece in question was not intended for public display.
- The material was only displayed in the UniChem Pharmacy in Ponsonby, inadvertently by the pharmacist, without RB's knowledge.
- RB has acted swiftly to ensure that the material was taken down and confirmed that the material was taken down.
- RB considers this matter to be closed.

The full correspondence between RB and AFT are attached.

Further, RB is prepared to undertake to ensure that the detailer which is the subject of this complaint is not used again in the future.

RB is concerned that AFT is misusing the ASA complaints procedure in this instance given that the Nuromol detailer which is the subject of this complaint has not been in circulation since April 2017 and all detailers were destroyed on 27th April 2017.

COMMENT FROM COMPLAINANT, AFT PHARMACEUTICALS TO ADVERTISER, RECKITT BENKISER'S RESPONSE

We believe Reckitt Benckiser's (RB) response letter dated 20^{1h} September 2017, once again, fails to address any of the aforementioned valid issues raised by AFT Pharmaceuticals (AFT).

We have repeatedly stated that we acknowledge, understand, and therefore do not contest that the material was not deliberately intended for public display, that it was for healthcare professionals, and that it has been taken down.

Nonetheless, we believe that as outlined in our complaint, the material still breached the Advertising Standards Authority (ASA) Therapeutic and Health Advertising Code. Additionally, whether intentional or not, it was in fact displayed to consumers, and it was intentionally used to promote to Healthcare Professionals for a period of time.

RB has stated that the material was developed for Healthcare Professionals and that it was not intended to be left behind. Regardless, whether or not it was used as a leave behind, we believe the material was still misleading and in breach of the code. All materials provided to healthcare professionals must adhere to the code. The points outlined by RB as above, we believe, were irrelevant in addressing our concerns in our letter.

In fact we do raise a point of serious concern that RB would appear to be somehow relying upon the promotional piece not being a leave behind in order to avoid valid scrutiny of compliance with accepted ASA promotional Advertising Codes.

Further to this point, when asked for clear substantiation on claims that have been challenged, RB has avoided these valid requests and stated that the piece has been superseded — however, this information was omitted in previous correspondence between RB and AFT. The only information provided by RB in our correspondence was the fact that the advertisement was intended for healthcare professionals, the advertisement was placed into open pharmacy independent of RB, and that it was taken down as a matter of urgency. There was no mention of the fact that this material was superseded, has been out of circulation since April 2017, and/or was destroyed on 27th April 2017. We note though that the material was still in circulation at the time of our original complaint (August 7th 2017) which is after this date, regardless of RB's contention to the contrary.

We are waiting for substantiation of the claims made within this advertisement as we believe RB has communicated and published misleading material. In particular, we believe RB has inappropriately and unfairly portrayed Maxigesic, by using misleading and vague claims as outlined in our complaint to the ASA. Consequently, if our view is upheld, then RB has used these claims to an unknown but likely significant number of Healthcare Professionals over a significant period of time which is still against the code regardless of whether they have now suddenly discontinued this promotion.

We do not believe we have misused the ASA complaints procedure as we are genuinely concerned about the potentially misleading claims used in RB's advertising material. We would like to ensure that the ASA code is adhered to and if it is not then sufficient remedial actions are undertaken to address the misleading claims.

In all of our correspondence, which was in good faith, we believe RB has not addressed our concerns regarding the content of the material. In fact, we suggest that their conduct has been evasive and not in good faith. Furthermore somehow relying upon the piece not being a leave behind in our view castes further doubts.

AFT is concerned about the potential damage that misleading comparative advertising can cause, both now and in the future, whether or not the material is superseded. We strongly maintain that the ASA process is not being abused by AFT and that this complaint should proceed in order to receive proper evaluation of the previously outlined concerns regarding potential breach(es) of the code.

RESPONSE FROM MEDIA, GREEN CROSS HEALTH

Just to confirm that **I** have taken the following action regarding the complaint received:

I am confident that the promotional material provided by the manufacturer was displayed by 1 pharmacy and they did so on the belief that the manufacturer had met all the requirements around advertising standards. They removed the material immediately when advised by the manufacturer. We have sent a communication to all pharmacies outlining the code of ethics that should be followed at all times around advertising in line with Pharmacy Council of New Zealand and that all material received Our Merchandising Team have been advised in writing that in future when working with suppliers that they are asked to confirm that all promotional and educational material used has TAPS approval prior to being distributed to pharmacies and that no material should be available without the appropriate TAPS approval.

I trust that the above provides sufficient information around the action that has been taken. Please do not hesitate to contact me should you require any further information or clarification.