

OUTCOMES OF COMPLAINTS LODGED UNDER THE ASMI CODE OF PRACTICE 07/08

Complaint 01/08

Complainant: Schering-Plough Pty Ltd (SP)

Respondent: GlaxoSmithKline Australia Pty Ltd (GSK)

Complaint: Advertising and promotion for "Beconase 12 Hour and Beconase 24 Hour" directed towards consumers in television commercials, pamphlets, consumer survey promotion, and a series of printed advertisements directed at doctors, pharmacists, pharmacy assistants and consumers.

Alleged Breaches:

Schering-Plough alleged the following breaches of the ASMI Code:

1. Clause 5.1.3: The daim "*Instead of taking antihistamine tablets, Becky prevents allergies with Beconase 24 Hour because Becky knows Beconase works*" was misleading as it made an absolute statement about the efficacy of Beconase
2. Clause 5.1.3: GSK failed to reflect the body of scientific evidence in the daim as it implied that antihistamine tablets are not able to prevent or effectively treat allergy symptoms.
3. Clause 5.1.3: The daims "*Unlike antihistamines, Beconase can prevent hay fever before it starts*" and "*RESEARCH has shown that unlike antihistamine tablets, Beconase Allergy & Hay fever nasal spray helps prevent symptoms from occurring, as well as treating them*" was misleading due to lack of substantiation of the daim. The second daim "*RESEARCH has shown that unlike antihistamine tablets*" was misleading in implying that comparative research shows that antihistamines are unable to prevent hay fever and allergy symptoms from occurring.
4. Clause 5.1.3: The daim "*FACT 2: INCS outperforms single active antihistamines for runny nose, sneezing, itching and blockage*" was misleading and does not reflect the current body of evidence as it conveys the message that INCS are more efficacious than antihistamines based upon outdated references.
5. Clause 5.1.3: The daim "*FACT 3: INCS are also recommended over antihistamines by ARIA allergy guidelines for moderate to severe allergic rhinitis*" is not supported by the ARIA Allergy guidelines released 2001, 2004 or 2007.
6. Clause 5.1.3: The daims "*For moderate to severe sufferers of hayfever and allergy, INCS are recommended over antihistamines by allergy specialists*" and "*Did you know? Intranasal Corticosteroid Spray (INCS) like Beconase are recommended by allergy experts to be used for most sufferers requiring long term treatment*" are misleading as they are not consistent with the body of scientific evidence
7. Clause 5.1.3: The daim of absolute efficacy "*Allergy Freedom*" was misleading because no therapy can ever guarantee total relief from all symptoms.
8. Clause 5.1.3: The daim "*using Beconase 2 weeks before Spring can help prevent the onset of hayfever*" failed to reflect the current body of evidence as it promoted the prophylactic use of Beconase for 2 weeks, which is substantially longer than the "few days" which are recommended in the relevant PIs for the products.
9. Clause 5.1.3: The daim "*Becky knows she can do the dusting without cleaning out a box of tissues*" was misleading by implying that Beconase 24 Hour can be used daily year round

“Becky knows her boyfriend’s flowers won’t make her teary eyed” (Attachment 8); “Just one spray daily can let them enjoy life without the worry of symptoms such as runny nose, watery eyes or that groggy, stuffed up feeling”, were unsubstantiated because INCS provide only modest benefit with respect to the treatment of eye symptoms.

11. Clause 5.2.1: That there was an implication that Beconase is more effective than antihistamines in treating eye symptoms.
12. Clause 5.1.3: The advertisement containing the claim *“Becky knows her boyfriend’s flowers won’t make her teary eyed”* using the imagery of flowers in relation to the control of eye symptoms was misleading by implying that Beconase 24 Hour can provide immediate relief from allergy symptoms. The advertisement contains the claim *“Help prevent them with Beconase Allergy 24 Hour”* which would mislead consumers to conclude that it is necessary to take Beconase in advance of being exposed to flowers in order to prevent allergy symptoms.
13. Clause 5.1.3: The claims relating to ‘groggy’ were misleading by implying that Beconase is effective in relieving a symptom identified as “groggy”.
14. Clause 5.1.3: The section entitled “What to recommend” in the counter unit, aiding pharmacy assistants, contains the message that patients whose allergy symptoms are moderate to severe whether persistent or occasional should be taking Beconase. Claims were misleading as the counter unit encouraged long term use of Beconase for more than 6 months.
15. Clause: 5.1.3: The claim *“Just one spray daily”* was inaccurate because the dosage instructions for the product require 2 sprays in each nostril.

Outcomes

The ASMI Complaints Panel found:

1. That the absolute statement of efficacy claim, “Becky prevents allergies with Beconase 24 Hour”, is accurate. This aspect of the complaint was dismissed.
2. That the claim does not imply that antihistamines are not effective as the advertisement does not refer to treatment and viewers would understand the difference between treatment and prevention. This aspect of the complaint was dismissed.
3. That the claim *“Unlike antihistamines, Beconase can prevent hayfever before it starts”* is accurate as Beconase 24 Hour is approved by the TGA for the prevention of hay fever whereas antihistamines are not and therefore, the Panel found that no substantiation is required. This aspect of the complaint was dismissed. The second claim was likely to convey to consumers that comparative research has shown that antihistamines do not have a prophylactic effect. This was found to be a moderate breach of clause 5.1.3 of the Code.
4. That the claim *“INCS outperforms single active antihistamines”* is not supported by the body of evidence and is a moderate breach of clause 5.1.3 of the Code.
5. That the claim *“INCS are also recommended over antihistamines by ARIA allergy guidelines”* is misleading and a moderate breach of clause 5.1.3. of the Code
6. That the claim *“INCS are recommended over antihistamines by allergy specialists”* is misleading as it extends to moderate to severe intermittent allergic rhinitis where the body of scientific evidence does not support that claim. This was found to be a moderate breach of clause 5.1.3 of the Code. In the Panel’s view, the second claim refers specifically to ‘long term treatment’ and would be read as a reference to persistent symptoms. This was also found to be a moderate breach of clause 5.1.3 of the Code.
7. That the claim “Allergy Freedom” would be interpreted by the average reader to be

8. That in regards to the approved PI for the products, GSK ought not to be promoting prophylactic use of its product for more than the time recommended in the PIs; "a few days" does not amount to 2 weeks. The claim "*using Beconase 2 weeks before Spring*" was found to be a minor breach of the clause 5.1.3 of the Code.
9. That the claim "*Becky knows she can do the dusting without cleaning out a box of tissues*" would not incite the average reader to assume that Beconase could be safely used for a whole year. This aspect of the complaint was dismissed.
10. That the claims relating to eye symptoms were misleading as they are not supported either by the PI or the body of scientific evidence. This was found to be a moderate breach of the clause 5.1.3 of the Code.
11. That the claims relating to eye symptoms are not comparative. This aspect of the complaint was dismissed.
12. That the advertisement which uses imagery of flowers in relation to control of eye symptoms was not misleading to say that use of INCS as a prophylactic will be effective to avoid watery eyes. The Panel noted that some consumers may believe that the flowers are being presented to "Becky" in the context in which she is receiving flowers may be interpreted by some consumers to mean that she can obtain immediate effect by using Beconase. On balance, this was found to be misleading and a moderate breach of clause 5.1.3 of the Code.
13. That the claims relating to "groggy" would not be read by the average reader as meaning a separate symptom. This aspect of the complaint was dismissed.
14. That "What to recommend" claims were not consistent with the ARIA or the MIMS guidelines. This was found to be a moderate breach of clause 5.1.3 of the Code. It was found that the claims on the front of the panel do not encourage use of Beconase for more than 6 months. This aspect of the complaint was dismissed.
15. That the claim "*Just one spray daily*" was misleading and in breach of clause 5.1.3 of the Code.

Sanctions: The Panel ordered GSK to:

- a. Discontinue the practice of advertising or otherwise communicating that research has shown that antihistamine tablets are unable to prevent hay fever and allergy symptoms from occurring;
- b. Discontinue the practice of comparing INCS with antihistamines and making any claims to the effect that INCS perform better than single active antihistamines, or that ARIA allergy guidelines recommend INCS over antihistamines;
- c. Provide written undertaking that it will not promote the prophylactic use of Beconase 12 Hour and 24 Hour products and any immediate symptomatic relief claims.
- d. publish corrective advertisements, and;
- e. Send to every pharmacist in Australia to whom the advertising and promotional material was likely to have been exposed a corrective letter.
- f. Pay a fine of total sum of \$20000 for all the Moderate Breaches.

Complaint 02/08

Complainant: GlaxoSmithKline Australia Pty Ltd (GSK)

Respondent: Johnson & Johnson Pacific Ltd (JJP)

Complaint: Consumer, trade and healthcare professional advertising campaign for smoking cessation support programme Nicorette ActiveStop. GSK complained against the "4 times" efficacy claim in all its forms, with words to the effect: "*if you use Nicorette and ActiveStop together; you're up to 4 times more likely to give up for good compared with willpower alone*".

Alleged Breaches:

GSK alleged the following breaches of the ASMI Code:

1. Clause 5.1.3: The "4 times" efficacy claim was not based on sound and objective evidence. It was not substantiated as there is no clinical evidence that Nicorette ActiveStop programme increases the chance of quitting. It was alleged that the claim was inaccurate and misleading. JJP has used inappropriate references to estimate

2. Clause 5.1.4: JJP failed to provide appropriate substantiation without delay upon request

Outcomes:

The ASMI Complaints Panel found:

1. That the '4 times' or 'upto 4 times' claim was unsubstantiated and misleading. The indirect comparison using odds ratios did not qualify the claim and since there has been no clinical study conducted comparing Nicorette + ActiveStop versus will power alone, the claim cannot be substantiated. JJP has failed to demonstrate that NRT combined with ActiveStop is up to 4 times more likely to lead to quitting than will power alone. This was found to be a Moderate breach of clause 5.1.3 of the Code.
2. That JJP did not provide appropriate substantiation in a timely manner. This was found to be a Minor breach of clause 5.1.4 of the Code.

Sanctions: The Panel ordered JJP to:

- a. Discontinue the practice of advertising or otherwise communicating the claim that a smoker using Nicorette together with the ActiveStop program is up to 4 times more likely to quit, compared with will power alone;
- b. Publish corrective advertisements, and;
- c. Send to every pharmacist in Australia to whom the advertising and promotional material was likely to have been exposed a corrective letter.

Complaint 03/08

Complainant: Schering-Plough Pty Ltd (SP)

Respondent: GlaxoSmithKline Australia Pty Ltd (GSK)

Complaint: Advertisements for Becoderm-C Flare-up Cream entitled "Treat eczema like an 'ex'" directed to healthcare practitioners in four trade journals. Advertisements for Becoderm Concentrated Rehydration entitled "Treat eczema like an 'ex'" and "You're in control" directed to pharmacy assistants in two journals.

Alleged Breaches:

SP alleged the following breaches of the ASMI Code:

1. Clause 5.1.3: The advertisements were making positive promotional statements without providing information on the appropriate cautions and contraindications. There was omission on mandatory information required by Section 5.5.1 of the Code.
2. Clause 5.1.3 and 5.1.4: The 5-day claim "The symptoms of eczema will be cleared up in as little as 5 days" was not supported by the scientific literature referenced (*Caramia et al*) and was not substantiated.
3. Clause 5.1.3: The rapid relief claim "Proven to provide rapid relief of eczema symptoms and promote healing" was not supported by the scientific literature referenced. It was alleged that "promote healing" would be understood by both healthcare professionals and the public as referring to the healing of wounds and the expression was inconsistent with the Becoderm-C PI, which says: "topical corticosteroids inhibit wound healing processes".
4. Clause 5.2: The 'one of the fastest' comparative claim "it's one of the fastest ways to show eczema flare-up the door" does not make clear with what the comparison is being made and was false since there are prescription products which relieve symptoms faster.
5. Clauses 5.1.3: GlaxoSmithKline failed to make it clear that Becoderm-C is indicated and should therefore be used only for milder forms of eczema. All the advertisements represent that it is effective in treating any severity of eczema, thus GlaxoSmithKline was promoting use outside the approved indications.
6. Clause 5.1.4: The claims "Treat eczema like your 'ex'" and "You're in control" in relation to Becoderm Concentrated Rehydration were not substantiated.
7. Clause 5.1.3: The advertisement with the claim "an effective new product for eczema

Outcomes:

The ASMI Complaints Panel found:

1. That the omission would have misled some pharmacists into the erroneous assumption that there are no contraindications, clinically significant precautions or side effects. This was found to be a breach of clause 5.5.1 of the Code. The Panel found that the omission of mandatory information was a moderate breach of clause 5.1.3 of the Code.
2. That the 5-day claim represents to the target audience that the product gets rid of eczema in no more than 5 days. This was not supported by the evidence, in breach of clause 5.1.3 and 5.1.4 of the Code.
3. That the rapid relief claim was not supported by the provided reference. This was found to be a moderate breach of clause 5.1.3 of the Code. The Panel did not accept SP's submission that "promote healing", in its context, would be understood as referring to the healing of wounds, nor that the notion of healing would be likely to result in the target audience thinking that Becoderm-C is for use in cases of eczema which predominantly involve weeping lesions, blisters or scabs. Rather the claim would be interpreted as "encouraging healing of the symptoms of eczema and dermatitis". This aspect of the complaint was dismissed.
4. That the 'one of the fastest' claim failed to identify with what the comparison was being made. This was found to be a moderate breach of clause 5.2 of the Code.
5. GlaxoSmithKline failed to make it clear that Becoderm-C is indicated and should therefore be used only for milder forms of eczema. Since the confined indication was not brought to attention of audience GlaxoSmithKline was promoting use outside the approved indications. This was found to be a moderate breach of clause 5.1.3 of the Code.
6. That the claims "*Treat eczema like your 'ex'*" and "*You're in control*" in relation to Becoderm Concentrated Rehydration were acceptable puffery. This aspect of the complaint was dismissed.
7. That the advertisement with the claim "*an effective new product for eczema and dermatitis*" goes beyond symptomatic relief and misrepresented the approved indications. This was found to be a moderate breach of clause 5.3.1 of the Code.

Sanctions: The Panel ordered GlaxoSmithKline to:

- a. Discontinue the advertisements in relation to Becoderm-C Flare-up Cream found to be in breach of the Code until they can be supported by clinical evidence
- b. Publish half page corrective advertisements in relation to Becoderm-C Flare-up Cream in relevant publications.
- c. Send to all Australian dermatologists to whom the advertising and promotional material was likely to have been exposed a corrective letter
- d. Discontinue the advertisement in relation to Becoderm Concentrated Rehydration found to be in breach of the Code.
- e. Publish a half page corrective advertisement in relation to Becoderm Concentrated Rehydration in relevant publications.
- f. Pay the following fines:
 - i. for the five Moderate Breaches in relation to Becoderm-C Flare-up Cream, a total fine of \$20,000; and for the Moderate Breach in relation to Becoderm Concentrated Rehydration, \$10,000.