

COMPLAINANT v RECKITT BENCKISER

Promotion of Gaviscon

A complainant who described him/herself as a concerned UK health professional, drew attention to an email he/she had received from Pulse Daily which included a highlighted box which stated 'How confident are you evaluating whether an infant requires pharmacological therapy for their reflux symptoms? Read our case study'. A foot note stated that the content hub was funded by Reckitt Benckiser but that the views and opinions expressed represented those of the doctors and not those of Reckitt Benckiser. Reckitt Benckiser marketed various formulations of Gaviscon (sodium alginate/potassium hydrogen carbonate) for the symptomatic relief of reflux in adults and to help prevent gastric regurgitation in infants.

The complainant stated that there was nothing in the email to suggest that it contained promotional material. The advertisement itself did not state that it was promotional and it did not contain prescribing information and it was thus disguised promotion. The complainant submitted that the reference to a 'case study' and that the views contained therein were not those of Reckitt Benckiser led him/her to assume that it was a non-promotional resource– however, access to the website showed that this was not so.

The complainant noted that the highlighted box linked to sponsored information hosted on the Pulse website in an educational hub which was a promotional feature aimed at clinicians to use Gaviscon. There was no generic name for the product, no prescribing information and no indication for use.

The complainant noted that the webpage itself stated that it was funded by Reckitt Benckiser, and it appeared to indicate that the clinicians had had the final editorial control and so there were again attempts to disguise that the material was paid-for promotional content.

The complainant alleged that a claim that Gaviscon got to work 'instantly' on a different page of the website was not supported by the summary of product characteristics (SPC) and noted that there was a difference between something that was rapid and something that was instant.

The complainant also noted that the page made claims in a table with text below which qualified that certain statements were only true of some of the Gaviscon range of products. This was not clear and the impression given was that the claims related to Gaviscon in general.

The complainant noted that the bottom of the web page included a link to the prescribing information for the products. The prescribing information was one of the only clues that

there were several Gaviscon products. The complainant alleged that the prescribing information was out-of-date.

The complainant noted that the bottom of the page stated: ' Please note, the Gaviscon tab is promotional content brought to you by Reckitt Benckiser. Initiated, funded and reviewed by Reckitt Benckiser...'. Reckitt Benckiser appeared to be stating that the other pages were not promotional and only the last page was – even though the link from the advertisement in the initial email linked through to the first page and not the last page.

In conclusion, the complainant stated that the material was a poorly constructed muddle of items where it was extremely confusing as to who had controlled or created what. The complainant alleged that due to how it was used, the whole content should be promotional.

The detailed response from Reckitt Benckiser is given below.

The Panel noted that the Gaviscon range of products which included Gaviscon Double Action, Gaviscon Advance and Gaviscon Infant were all over-the-counter medicines which could be bought by members of the public without a prescription. Advertisements designed to encouraged doctors to prescribe Gaviscon, however, would come within the scope of the ABPI Code.

The Panel noted that the highlighted box was signed off on a form entitled 'Certificate for promotional material'. In the Panel's view the highlighted box which did not mention any products although made a general statement in relation to pharmacological therapy for reflux was not in itself promotional and a link to prescribing information was not needed and the Panel therefore ruled no breach of the Code.

The Panel noted, however, that it was not clear from the highlighted box in the email that the reader would be taken to a website which promoted Gaviscon. The Panel ruled a breach of the Code as the promotional nature of the website the reader was directed to had thus been disguised.

Readers were told that the content hub was funded by Reckitt Benckiser but that the views and opinions expressed represented those of the doctors and not those of Reckitt Benckiser. The company had, however, approved material on the content hub including case studies and had created the Gaviscon tab. In the Panel's view, the wording of the disclaimer was not such that readers would immediately understand the extent of the company's involvement or influence over the material. A breach of the Code was ruled.

The Panel noted Reckitt Benckiser's submission that clicking on the link in the highlighted box would take the reader to the home page of the upper gastrointestinal condition education hub. That home page featured a number of patient case studies including one about managing gastro-oesophageal reflux in infants which was alluded to in the highlighted box. One section of the case study was headed 'When should I prescribe alginates?'. In all of the other four case studies of patients with various needs, the prescription of alginates was discussed and the material had been approved by Reckitt Benckiser and originated in-house. The Panel noted that although Gaviscon *per se* was not mentioned in the case studies, the prescription of alginates was and the Gaviscon tab could be seen in the top right of the screen when viewing the case studies.

The content of the Gaviscon tab was clearly promotional and specifically referred to prescription (NHS packs) of Gaviscon Double Action and Gaviscon Advance. The Panel thus considered that the educational hub as a whole promoted Gaviscon for prescription and in that regard, it had to comply with the ABPI Code.

With regard to the requirements to include the non-proprietary name immediately adjacent to the most prominent display of the brand name, the Panel considered that in this instance Gaviscon might be seen as the brand name for all the formulations and it might have been helpful to list all the medicines and their non-proprietary names in association with the first use of Gaviscon. Nonetheless, given there was no product named simply Gaviscon the non-proprietary name was not technically needed and the Panel ruled no breach of the Code.

The Panel noted Reckitt Benckiser's submission that the prescribing information provided in relation to the Gaviscon tab was up to date. The complainant had provided no details or evidence in this regard and so the Panel ruled no breach of the Code.

The Panel noted that whilst the Gaviscon tab included a link to prescribing information, in the Panel's view, noting its comments above, the entire website promoted Gaviscon and there should have been a clear prominent statement as to where the prescribing information could be found on the landing page following the link from the advertisement. A breach of the Code was ruled.

The Panel noted that in the Gaviscon tab there was a claim that Gaviscon Advance and Gaviscon Double Action 'Gets to work instantly'. The claim was referenced to Hampson *et al*, an in vitro study which tested the effectiveness of raft formation of a range of alginate/antacid anti-reflux liquid preparations. The authors did not refer to the instant action of any of the medicines but did refer to their rapid action. The Panel further noted that the SPCs referred to rapid action, not instant action; in the Panel's view, there was a difference between the two. The Panel considered that the claim for 'instant' action was not supported by the SPC as alleged. It was misleading and inaccurate and the Panel ruled a breach of the Code.

The complainant referred to claims in a table and that the initial impression was that it related to Gaviscon in general but text below qualified that certain statements were only true of some of the Gaviscon range of products. The complainant did not provide any specific details and Reckitt Benckiser had not responded to this allegation. When reviewing the page the Panel was unclear to which table the complainant referred. It was for the complainant to establish his/her case on the balance of probabilities. It was not for the Panel to make out a complainant's allegation and the Panel therefore made no ruling in relation to this matter.

The Panel noted its comments and rulings above and considered that Reckitt Benckiser had failed to maintain high standards and a breach of the Code was ruled.

The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of the Code was ruled.

A complainant who described him/herself as a concerned UK health professional, drew attention to an email he/she had received from Pulse Daily which was sent from the journal to keep readers up-to-date with 'the latest GP news, views and analysis'. The subject heading of the email was 'Coronavirus patients can call 111 to get email confirmation instead of GP sick note'. Embedded in the email, which covered a number of other news items, was a highlighted box (ref RM-M-01048) which stated 'How confident are you evaluating whether an infant requires pharmacological therapy for their reflux symptoms? Read our case study'. A foot note stated that the content hub was funded by Reckitt Benckiser but that the views and opinions expressed represented those of the doctors and not those of Reckitt Benckiser. Reckitt Benckiser marketed various formulations of Gaviscon (sodium alginate/potassium hydrogen carbonate) for the symptomatic relief of reflux in adults and to help prevent gastric regurgitation in infants.

COMPLAINT

The complainant stated that there was nothing in the email to suggest that it contained promotional material. The advertisement itself did not state that it was promotional and it did not contain prescribing information. The complainant submitted that the reference to a 'case study' and the statement that the views contained therein were not those of Reckitt Benckiser led him/her to assume that it was a non-promotional educational resource— however, access to the website showed that this was not so. The complainant stated that the highlighted box did not have a link to the prescribing information and alleged it was disguised promotion.

The complainant noted that the highlighted box linked to sponsored information hosted on the Pulse website in an educational hub. The information was a promotional feature aimed at clinicians to use Gaviscon. There was no generic name for the product, no prescribing information and no indication for use.

The complainant noted that the webpage itself stated that it was funded by Reckitt Benckiser, and it appeared to indicate that the clinicians had had the final editorial control: 'This content hub is funded by Reckitt Benckiser. The views and opinions presented here represent those of the doctors and do not reflect those of Reckitt Benckiser.' and so there were again attempts to disguise that the material was paid-for promotional content by a pharmaceutical company.

The complainant alleged that a claim that Gaviscon got to work 'instantly' on a different page of the website was not supported by the summary of product characteristics (SPC) and noted that there was a big difference between something that was rapid and something that was instant.

The complainant also noted that the page made claims in a table with text below which qualified that certain statements were only true of some of the Gaviscon range of products. This was not clear and was not the first impression given – it appeared that the claims related to Gaviscon in general.

The complainant noted that right at the bottom of the web page there was a link to the prescribing information for the products. The prescribing information was one of the only clues that there were several Gaviscon products. The complainant alleged that the prescribing information was out-of-date.

The complainant noted that right at the bottom of the page was the following: 'Click here for the prescribing information. Please note, the Gaviscon tab is promotional content brought to you by Reckitt Benckiser. Initiated, funded and reviewed by Reckitt Benckiser. UK/G-

NHS/0818/0015a. Date of preparation: October 2018'. The complainant stated that he/she initially overlooked that completely. In his/her view, Reckitt Benckiser appeared to be stating that the other pages were not promotional and only the last page was – even though the link from the advertisement in the initial email linked through to the first page and not the last page.

In conclusion, the complainant stated that the material was a poorly constructed muddle of items where it was extremely confusing as to who had controlled or created what. The complainant alleged that due to how it was used, the whole content should be promotional and it was deeply concerning that Reckitt Benckiser had undertaken such a hybrid activity.

The complainant submitted the exact same complaint approximately 6 weeks later. The complainant was invited to withdraw the second complaint in accordance with Paragraph 15.1 of the Constitution and Procedure, but he/she has declined to do so. The Case Preparation Manager decided to amalgamate the cases so that, in effect, both cases would be considered as one complaint.

When writing to Reckitt Benckiser in relation to Case AUTH/3316/3/20, the Authority asked it to consider the requirements of Clauses 4.1, 4.3, 7.2, 9.1 and 9.10, and to note the supplementary information to Clause 9.10 in relation to material circulated by third party journals. In addition to the above clauses, when writing to Reckitt Benckiser in relation to Case AUTH/3330/4/20, the Authority asked it to consider the requirements of Clauses 12.1 and 2.

RESPONSE

Reckitt Benckiser noted that it was a consumer healthcare business with a range of medicines in its gastrointestinal portfolio which included Gaviscon. The medicines in the gastrointestinal portfolio were not prescription only medicines and so could be purchased by consumers over the counter or recommended for purchase by health professionals. Although the medicines could be prescribed, this was not routine practice which was consistent with guidance from NHS England on minor ailments which recommended that medicines should not be prescribed for conditions for which over-the-counter medicines were available. Therefore, the applicable advertising regulations and codes must be applied for each scenario.

Reckitt Benckiser submitted that its promotional materials were always subject to robust internal procedures to ensure the highest standards, including the Code, were strictly adhered to. The NHS landscape was moving towards self-care as noted above and health professionals now recommended certain products for purchase rather than prescribing.

Reckitt Benckiser stated that the overall content on the Pulse website was intended to act as an educational tool for health professionals in respect of upper gastrointestinal conditions. The content varied depending on the tab chosen by the viewer. There were five different tabs – 'Home' contained educational content including a number of case studies, 'Physiology' contained content relating to pathophysiology, 'Interventions' contained content relating to interventions, 'Challenges for Primary Care' contained therapy area related content and 'Gaviscon' which contained content specific to some Gaviscon upper gastrointestinal medicines.

Reckitt Benckiser submitted that the initial email to which the complainant referred was sent to health professionals. If viewers clicked on the link in the email they were taken to the Home tab only. The content on the Home tab did not contain any information about Reckitt Benckiser medicines – it only provided information on classes of medicines and patient case studies.

There was, however, a clear statement at the bottom of the page that made it clear that the content was sponsored by Reckitt Benckiser but not produced by the company ie 'This content hub is funded by [Reckitt Benckiser]. The views and opinions presented here represent those of the doctors and do not reflect those of [Reckitt Benckiser]'.

Reckitt Benckiser noted, however, that it had identified a slight difference between the material that was certified and the material that went live on the Pulse website. The home page as certified did not have the Gaviscon trademark on it but in February 2020 the Gaviscon trademark appeared inadvertently on the right-hand side of the page. Once identified, the Gaviscon trademark was immediately removed.

With regard to the requirements of Clause 4.1, Reckitt Benckiser stated that it did not agree with the complainant's assertion that the materials did not contain the prescribing information as required by the Code. The company noted that the complainant contradicted him/herself in that he/she also stated that the prescribing information appeared in a piece of disguised promotion and was out-of-date, both assertions of which the company disagreed; the complainant had also acknowledged that the prescribing information had been provided. The prescribing information was up-to-date and was provided in a clear and legible manner on the Gaviscon tab with a clear statement at the bottom of the page: 'Please note, the Gaviscon tab is promotional content brought to you by Reckitt Benckiser'. Reckitt Benckiser stated that the prescribing information was consistent with the SPC. In line with the Code, there was a clear and prominent direct single click link to the prescribing information with the statement 'Click here for the prescribing information'. Reckitt Benckiser submitted that all requirements of Clause 4.1 had therefore been met.

With regard to Clause 4.3, which required the non-proprietary name of a medicine to be listed immediately adjacent to the most prominent display of the approved name, Reckitt Benckiser did not agree with the complainant's assertion that there was no generic name for the medicines in the materials presented. Reckitt Benckiser noted that 'Gaviscon' in and of itself was not an approved product name. As such, when used in isolation the non-proprietary name/list of active ingredients did not need to be listed adjacent to it. In consumer healthcare, the word 'Gaviscon' on its own was used as a trademark for a portfolio which consisted of a breadth of approved products with approved names such as Gaviscon Advance, Gaviscon Double Action and Gaviscon Infant, in accordance with the SPC. Reckitt Benckiser noted that the list of the active ingredients appeared immediately adjacent to the most prominent display of the approved medicine names in a table of data in the Gaviscon tab which listed Gaviscon Advance, Gaviscon Double Action and Gaviscon Infant. The table was clearly distinct from the remainder of the page and prominently displayed. These approved medicines could be purchased over the counter, recommended to consumers to purchase or could be prescribed, and as such the rules of the Code in respect to Clause 4.3 had been applied where there was information covering the prescription of the relevant approved medicine.

Furthermore, the active ingredients were clearly displayed at first mention of the prescription of any of the approved medicines in the range, in accordance with the transparency requirements of the Code. An extract of the table as it appeared on the website was provided.

Reckitt Benckiser submitted that the claim that Gaviscon Advance and Gaviscon Double Action, both of which contained a combination of antacid and an alginate, got to work 'instantly' was substantiated by Hampson *et al* (2005) which referred to the rapid onset of action of both medicines. Hampson *et al* was clearly cited on the page. The approved medicine, be it

Gaviscon Advance or Gaviscon Double Action, reached its site of action directly once swallowed and the raft began its formation instantly. It therefore got to work instantly. Gaviscon Advance and Gaviscon Double Action had a physical mode of action; they did not need to be absorbed into systemic circulation as stated in section 5.2 (Pharmacokinetic properties) of the SPC: 'The mode of action of Gaviscon Advance Aniseed Suspension is physical and does not depend on absorption into the systemic circulation'. The site of action of the medicine was in the stomach where it 'gets to work instantly' once swallowed. It was well established that when liquid was swallowed, it reached the stomach in 1-2 seconds. Therefore, once it was swallowed, the therapeutic dose of the medicine as per instructions had reached its site of action and got to work instantly.

Reckitt Benckiser noted that there was a clear and prominent declaration of the support the company had provided with respect to the content for each page on the website. Furthermore, the company logo appeared on each page in a prominent position so that the viewer could easily identify the sponsorship. The declaration 'This content hub is funded by Reckitt Benckiser' which appeared at the bottom of the home page, further stated 'The views and opinions presented here represent those of the doctors and do not reflect those of Reckitt Benckiser'. The role played by the company was clearly and accurately reflected in relation to the content on the pages.

Reckitt Benckiser submitted that as stated above, the content on the web pages did not breach the Code. The content was certified in good faith and in accordance with the requirements of the Code. As the company did not consider that it had breached any clauses of the Code, it did not consider that a ruling of a breach of Clause 9.1 was appropriate.

In summary, Reckitt Benckiser submitted that it took its obligations under the relevant industry codes, including the ABPI Code, seriously to ensure all materials were certified to a high standard. None of the materials at issue breached the Code.

In response to a request for further information with regards to Clauses 12.1 and 2 raised in Case AUTH/3330/4/20, Reckitt Benckiser noted that Clause 12.1 stated that promotional material sent electronically such as emails must not give the impression that it was non-promotional. Reckitt Benckiser explained that clicking the link within the email took the reader to the home tab only which did not contain any materials relating to Reckitt Benckiser medicines and was non-promotional. It provided information on classes of medicines and patient case studies and there was a clear statement 'This content hub is funded by RB. The view and opinions presented here represent those of the doctors and do not reflect those of RB.' at the bottom of the page that made it clear that the content although sponsored by Reckitt Benckiser was not produced by it. Should the recipient choose to navigate through to the Gaviscon page, there was also a transparent statement 'Please note, the Gaviscon tab is promotional content brought to you by RB'. The promotional and non-promotional pages were clearly separated and there was sufficient information for the reader to understand which sections were promotional and which were not.

Reckitt Benckiser further noted that Clause 12.1 stated that 'In addition the identity of the responsible pharmaceutical company must be obvious.' and submitted that the role of Reckitt Benckiser was obvious in the initial email. The Reckitt Benckiser logo as well as the declaration of involvement appeared on each page of the site and in a prominent position for the reader to easily identify the sponsorship. Reckitt Benckiser therefore strongly refuted the complainant's suggestion that it was disguised promotion.

Reckitt Benckiser noted that a ruling of a breach of Clause 2 was a sign of particular censure and was of the view that it had not breached any clause of the Code and as such respectfully submitted that its activities were not a breach of Clause 2.

PANEL RULING

The Panel noted that the Gaviscon range of products which included Gaviscon Double Action, Gaviscon Advance and Gaviscon Infant were all over-the-counter medicines which could be bought by members of the public without a prescription. The promotion of medicines for self-medication was covered by either one of the two codes administered by the Proprietary Association of Great Britain (PAGB) and not the ABPI Code. Advertisements designed to encourage doctors to prescribe Gaviscon, however, would come within the scope of the ABPI Code.

The Panel noted the complainant's concern that the advertisement (highlighted box, ref RB-M-01048) itself did not state that it was promotional and it did not contain prescribing information.

The Panel noted that the highlighted box was signed off on a form entitled 'Certificate for promotional material'. In the Panel's view the highlighted box which did not mention any products although made a general statement in relation to pharmacological therapy for reflux was not in itself promotional and a link to prescribing information was not needed as required by Clause 4.4. This clause had not been raised by the case preparation manager and the Panel therefore ruled no breach of Clause 9.1 in relation to this allegation.

The Panel noted, however, that it was not clear from the highlighted box in the email that the reader would be taken to a website which promoted Gaviscon. The Panel considered that the promotional nature of the website the reader was directed to had thus been disguised and a breach of Clause 12.1 was ruled.

Readers were told that the content hub was funded by Reckitt Benckiser but that the views and opinions expressed represented those of the doctors and not those of Reckitt Benckiser. The company had, however, approved material on the content hub including case studies and had created the Gaviscon tab. In the Panel's view, the wording of the disclaimer that the content hub had been funded by Reckitt Benckiser was not such that readers would immediately understand the extent of the company's involvement or influence over the material to which they were being directed. A breach of Clause 9.10 was ruled.

The Panel noted Reckitt Benckiser's submission that clicking on the link in the highlighted box which appeared in the email, would take the reader to the home page of the upper gastrointestinal condition education hub. That home page featured a number of patient case studies including one about managing gastro-oesophageal reflux in infants which was alluded to in the highlighted box. The content of that case study had been approved by Reckitt Benckiser. One section of the case study was headed 'When should I prescribe alginates?'. In all of the other four case studies of patients with various needs, the prescription of alginates was discussed and again the material had been approved by Reckitt Benckiser and originated in-house. The Panel noted that although Gaviscon *per se* was not mentioned in the case studies, the prescription of alginates was and the Gaviscon tab could be seen in the top right of the screen when viewing the case studies. The content of the Gaviscon tab was clearly promotional and specifically referred to prescription (NHS packs) of Gaviscon Double Action and Gaviscon

Advance. The Panel thus considered that the educational hub as a whole promoted Gaviscon for prescription and in that regard, it had to comply with the ABPI Code.

With regard to the requirements of Clause 4.3, the Panel noted Reckitt Benckiser's response regarding the requirements for the citing of approved product names and brand names. Clause 4.3 required the non-proprietary name of a medicine, or a list of the active ingredients using approved names where such exist, to appear immediately adjacent to the most prominent display of the brand name. The Panel considered that in this instance Gaviscon might be seen as the brand name for all the formulations and it might have been helpful to list all the medicines and their non-proprietary names in association with the first use of Gaviscon. Nonetheless, given there was no product named simply Gaviscon the non-proprietary name was not technically needed. The Panel ruled no breach of Clause 4.3.

The Panel noted Reckitt Benckiser's submission that the prescribing information provided in relation to the Gaviscon tab was up to date. The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had alleged that the prescribing information was out-of-date but had provided no details or evidence in this regard and so the Panel ruled no breach of Clause 4.1.

The Panel noted that whilst the Gaviscon tab included a link to prescribing information, in the Panel's view, noting its comments above, the entire website promoted Gaviscon and there should have been a clear prominent statement as to where the prescribing information could be found on the landing page following the link from the advertisement. This was a requirement of Clause 4.6 but that clause had not been raised by the Case Preparation Manager. The Panel therefore dealt with this point under Clause 9.1 and a breach of Clause 9.1 was ruled.

The Panel noted that the SPC for Gaviscon Advance Aniseed Oral Suspension stated in Section 5.1 that 'On ingestion the suspension reacts with gastric acid to *rapidly* form a raft of alginic acid gel ...' (emphasis added). Similarly, the SPC for Gaviscon Double Action Mint Oral Suspension stated 'On ingestion, the medicinal product reacts *rapidly* with gastric acid to form a raft of alginic acid gel ...' (emphasis added). In the Gaviscon tab there was a claim that Gaviscon Advance and Gaviscon Double Action 'Gets to work instantly'. The claim was referenced to Hampson *et al*, an in vitro study which tested the effectiveness of raft formation of a range of alginate/antacid anti-reflux liquid preparations. The authors did not refer to the instant action of any of the medicines but did refer to their rapid action. The Panel further noted that the SPCs referred to rapid action, not instant action; in the Panel's view, there was a difference between the two. Rapid, as per the SPC, referred to something happening in a short time or at great speed whilst instant referred to something happening immediately. The Panel considered that the claim for 'instant' action was not supported by the SPC as alleged. It was misleading and inaccurate and the Panel ruled a breach of Clause 7.2.

The complainant referred to claims in a table and that the initial impression was that it related to Gaviscon in general but text below qualified that certain statements were only true of some of the Gaviscon range of products. The complainant did not provide any specific details and Reckitt Benckiser had not responded to this allegation. When reviewing the page the Panel was unclear to which table the complainant referred. It was for the complainant to establish his/her case on the balance of probabilities. It was not for the Panel to make out a complainant's allegation and the Panel therefore made no ruling in relation to this matter.

The Panel noted its comments and rulings above and considered that Reckitt Benckiser had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

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During the consideration of this case the Panel was concerned to note Reckitt Benckiser's submission that it had identified a slight difference between the material that was certified and the material that went live on the Pulse website. The home page as certified did not have the Gaviscon trademark on it but in February 2020 the Gaviscon trademark appeared inadvertently on the right-hand side of the page.

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Complaints received 6 March 2020 and 14 April 2020

Cases completed 8 September 2020