CASE AUTH/2576/2/13

ANONYMOUS GENERAL PRACTITIONER v ABBOTT

Promotion of Hidrasec including via social media

An anonymous, non-contactable general practitioner complained about the promotion of Hidrasec (racecadotril). Hidrasec, marketed by Abbott Healthcare, was indicated for the treatment of acute diarrhoea in adults and infants (older than 3 months).

The detailed response from Abbott is given below.

The complainant found advertisements for Hidrasec on Facebook and a video about how it worked on another website. The video labelled 'Hidrasec Mode of Action' appeared to be aimed at patients and the complainant was concerned as to where else this was available and how it would be used with patients.

The complainant noted that Abbott marketed Hidrasec but the advertisements appeared to have been posted by the advertising agency. The complainant considered that the public should not be able to see these advertisements and was concerned that this sort of information could lead patients to request Hidrasec inappropriately.

The Panel noted that it appeared that in response to a request from the UK based photographer who took the original shots, Abbott global agreed to supply a copy of the images used in the advertising campaign. The images were for the photographer's portfolio on his/her Facebook site. The Panel questioned whether Abbott global had, in allowing the files to be sent to the photographer, realized that the text would be included.

The Panel noted that Facebook was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on a personal Facebook site. The Panel considered that placing the Hidrasec advertisements on Facebook in effect promoted a prescription only medicine to the public and encouraged members of the public to ask their health professional to prescribe it. Breaches of the Code were ruled. The Panel considered that high standards had not been maintained. A further breach of the Code was ruled. The Panel did not consider, however, that there had been a breach of Clause 2.

With regard to the mode of action video, the Panel noted that the video clip had been uploaded onto an animator's professional website. The Panel noted Abbott's submission that the uploaded version had been altered such that the only reference to Hidrasec was in the caption, 'Hidrasec "Mode of action" animation Abbott Laboratories Ltd. 2010', beneath the video clip. The Panel further noted that no record of the video as posted on the animator's website remained as Abbott had asked for it to be removed.

The Panel considered it was unfortunate that the caption to the video mentioned Hidrasec when mention of the product had been removed from the video. The Panel considered that as it had no idea of the content of the video it could not be certain that a prescription only medicine had been promoted to the public or that statements had been made which would encourage members of the public to ask their health professional to prescribe Hidrasec. Given these circumstances the Panel ruled no breach of the Code.

The complainant further complained that advertisements for Hidrasec, a new product, did not display a black triangle.

The Panel noted that the Code stated that when required by the licensing authority, all promotional material must show an inverted black triangle to denote that special reporting was required in relation to adverse reactions. It appeared that during the pre-vetting process, the licensing authority had not told Abbott that a black triangle was required. The product was added to the black triangle list in December 2012 and Abbott had amended its materials in January 2013 when the decision was confirmed. The Panel noted that Hidrasec material had not displayed the black triangle symbol for three months or so. The Panel noted that if there was a date on the material provided by the complainant it could not be read. The Panel considered that taking all the circumstances into account the complainant had not proved his/her complaint on the balance of probabilities. In addition the product had not been placed on the black triangle list until 3 months after it was first marketed. The Panel thus ruled no breach of the Code.

The complainant noted that as Hidrasec was only licensed for children over 3 months, Abbott could not claim that it 'provides rapid control for even your smallest patients'.

The Panel noted that Hidrasec was indicated, *inter alia*, for the complementary symptomatic treatment of acute diarrhea in infants aged over 3 months. The Panel noted that the claim at issue was preceded by the statement 'And because its licensed in infants older than 3 months …'. The Panel thus did not consider that the claim '... provides rapid control for even your smallest patients' was unacceptable as alleged; it was clearly within the context of infants older than 3 months and was thus not inconsistent with the particulars listed in the SPC. No breaches of the Code were ruled.

An anonymous, non-contactable general practitioner complained about the promotion of Hidrasec (racecadotril) and drew particular attention to material available to the public via Facebook and the Internet. Hidrasec 100mg capsules were indicated for the symptomatic treatment of acute diarrhoea in adults when causal treatment was not possible. A granular paediatric formulation was indicated as complementary oral rehydration therapy in infants (older than 3 months) with acute diarrhoea. Hidrasec was marketed by Abbott Healthcare Products Limited.

When writing to Abbott, the Authority asked it to respond in relation to Clauses 2, 3.2, 4.11, 7.2, 9.1, 22.1 and 22.2 of the Code.

1 Advertising on Facebook and the Internet

COMPLAINT

The complainant stated that whilst searching the Internet for information on Hidrasec he/she found advertisements for it on Facebook and a video about how it worked on another website. The video labelled 'Hidrasec Mode of Action' appeared to be aimed at patients and the complainant was concerned as to where else this was available and how it would be used with patients. The complainant provided links to the relevant Facebook page and Internet page.

The complainant noted that Abbott marketed Hidrasec but it appeared that the advertisements had been posted by the advertising agency. The complainant considered that it was wrong for the public to be able to see these advertisements for a prescription only medicine. The complainant was concerned that this sort of information could lead to patients requesting this product inappropriately. This was of particular concern to the complainant as Hidrasec had not been recommended for use by the Scottish Medicines Consortium (SMC). Although the complainant was based in England, he/she highly valued these assessments of new products and tended to follow their guidance.

RESPONSE

Abbott submitted that it became aware of the Hidrasec advertisements on Facebook on 8 November 2012 when a UK representative reported the matter to the UK Abbott affiliate. The advertisements corresponded to those developed by Abbott's global marketing team based in Basel, Switzerland. It was evident that the advertisements on Facebook had been changed from the original global versions as the majority of the footer text had been removed, however, they could be identified as originating from the global marketing team's materials and could be distinguished from UK specific advertisements by, *inter alia* the spelling of 'diarrhoea' (spelt diarrhea in the global material). For comparison, Abbott provided copies of the approved UK Hidrasec advertisements.

The Facebook site referred to by the complainant was that of the photographer and his/her photographic agency who worked on the photo shoot for the global Hidrasec campaign on behalf of the advertising agency. The site content concerned the professional activities of the agencies/photographer, including many examples of his/her work and technical considerations relating to his/her work. The images from the Hidrasec campaign had been provided with permission from Abbott global. There was never any intention behind this decision to promote Hidrasec to the public, the intention was only to allow the photographer to use the images he/she shot to advertise his/her work. The material was not intended for the UK audience.

Abbott stated that the UK company had a separate contract with its advertising agency to cover the development of UK specific advertisements. This agreement contained sections on intellectual property rights and advertising outside the territory. The UK contract referred separately to materials created as part of the proposal (for the exclusive use of Abbott) and photographic images (the ownership of photographic images, film and animation work was not assigned and was subject to licence agreements). The UK advertisements were therefore for the exclusive use of Abbott and there had been no subsequent permission granted by Abbott to allow use of the UK specific advertisements. Abbott submitted that it had not found any of its UK advertisements on the Internet.

Abbott stated that although it was clear that the images originated from its global team and no permission was granted for the purposes of advertising an Abbott product, Abbott considered it was good practice to telephone its advertising agency on 9 November, 2012 to ask for further information on how these materials might have been disseminated following the permission granted and request the immediate removal of the Hidrasec images from the Internet. The advertising agency immediately contacted the photographer's agent to request that he/she removed all images from Facebook as well as any other websites as soon as possible. The advertising agency confirmed its actions in emails dated 9 November.

Abbott stated that it commenced an investigation into the circumstances of both the advertisements and video appearing on the Internet and again contacted its advertising agency on 14 November to seek reassurances that materials had been removed. On 23 November its advertising agency again confirmed that the photographer's agent had removed the remaining advertising images.

Abbott did not consider that there was any attempt or intention on its part to advertise to the public. The photographer placed materials on his/her website to advertise his/her own work and no permissions were given by Abbott in the UK to place UK approved advertising on the Internet. As a result Abbott did not consider that there had been a breach of the Code. Furthermore the presence of the global advertisements not intended for a UK audience on the Internet fell outside the scope of the Code as outlined in Clause 1. Notwithstanding that there had been no breach of the Code, Abbott had taken all reasonable steps to have any images removed

from the Internet and also retrained relevant UK and global staff.

Abbott submitted that the mode of action video referred to by the complainant was also developed for the Abbott global marketing team. A screenshot corresponding with the image of the video clip on the website referenced was provided.

The video did not refer to Abbott nor was there any reference to Hidrasec or the generic name either verbally or in print as part of the video clip. The animated clip showed activities in the gut before and once diarrhoea occurred and a factual commentary to accompany it. In the commentary there was no reference to Hidrasec or racecadotril. The only reference to Hidrasec was in the caption beneath the video clip 'Hidrasec "Mode of action" animation Abbott Laboratories Ltd 2010'. The reference to 'Abbott Laboratories Ltd 2010' demonstrated that the video was produced under the global agreement and predated any UK marketing activities for the medicine.

The Internet site in question was that of the animation company which produced the video; the site detailed only the professional activities of the animation company and contained many examples of its work. Abbott stated that it had not received any request or other correspondence from its advertising agency or the animation company regarding the use of the video.

Hidrasec was licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) in September 2011 and it was commercialized in October 2012 and hence could be promoted in the UK regardless of the recent SMC decision not to recommend it.

As a result it appeared that a non-promotional video produced for the Abbott global campaign was placed on a professional Internet site by the animation company to display its work. Abbott thus did not consider that there had been a breach of the Code with regard to the promotion of Hidrasec to the public. Furthermore, the presence of global non-promotional videos not intended for a UK audience on the Internet fell outside the scope of the Code as outlined in Clause 1. However Abbott again considered it appropriate to ask for this material to be removed and had also retrained its staff as outlined above.

In response to a request for a copy of the mode of action video, Abbott submitted that the video referred to by the complainant was not the UK mechanism of action video. Abbott submitted that as this was a third party global altered version not intended for advertising the product but uploaded onto an animator's professional Internet site in order to display its work, and that as Abbott had asked for the link to be removed, it had no copies of the video to provide.

In response to a further request for more information, Abbott stated that Abbott's advertising agency, the photographer and the animation company were all based in the UK but all had an international client base with outputs shown globally. In addition the photographer was of international acclaim and had agents representing him/her in various countries around the world.

PANEL RULING

The Panel noted that it appeared that in response to a request from the photographer, Abbott global had agreed to supply a copy of the images used in the advertising campaign. The images were for the photographer's portfolio on his/her Facebook site. The photographer was based in the UK and so in that regard the Panel considered that the matter came within the scope of the Code. The Panel questioned the need for the images to be supplied complete with text and queried whether, in allowing the files to be sent to the photographer, Abbott global had realized that the text would be included and ascertained exactly what the photographer intended to do with the files.

The Panel understood that creative agencies and individuals would want to be able to show examples of their work. However pharmaceutical companies had to ensure that by facilitating such use, prescription only medicines were not advertised to the public. The structure of a website, the description of the materials and their content would be important factors.

The Panel noted Abbott's submission that the materials were from Abbott global and not Abbott UK and predated the promotion of Hidrasec in the UK.

It was a well established principle that UK pharmaceutical companies were responsible for the activities of overseas affiliates if such activities related to UK health professionals or were carried out in the UK.

The Panel noted that Facebook was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of pharmaceutical promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on a personal Facebook site. The Panel considered that placing the Hidrasec advertisements on Facebook in effect promoted a prescription only medicine to the public. A breach of Clause 22.1 was ruled. The Panel considered that statements had thus been made in a public forum which would encourage members of the public to ask their health professional to prescribe Hidrasec. A breach of Clause 22.2 was ruled.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider, however, that there had been a breach of Clause 2. Such a ruling was the sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

With regard to the mode of action video, the Panel noted that the video clip had been uploaded onto an animator's professional website. The Panel

noted Abbott's submission that the video had been developed for the global marketing team and that the version uploaded onto the animator's website had been altered to delete references to Hidrasec or racecadotril. The only reference to Hidrasec was in the caption beneath the video clip which read 'Hidrasec "Mode of action" animation Abbott Laboratories Ltd. 2010'. The Panel further noted that no record of the video as posted on the animator's website remained as Abbott had asked for it to be removed. The link to the video, provided by the complainant, no longer worked.

The Panel considered it was unfortunate that the caption to the video mentioned Hidrasec when mention of the product had been removed from the video. The Panel considered that as it had no idea of the content of the video it could not be certain that a prescription only medicine had been promoted to the public or that statements had been made which would encourage members of the public to ask their health professional to prescribe Hidrasec. Given these circumstances the Panel ruled no breach of Clause 22.1 and 22.2.

2 Absence of the inverted black triangle symbol

COMPLAINT

The complainant was also concerned that as a new product, Hidrasec should display a black triangle. The complainant had seen the same advertisements in medical journals and they did not show this. Surely this was a safety issue? The complainant stated that a copy of an advertisement from the journal 'Guidelines' was provided.

RESPONSE

Abbott noted that Hidrasec 10mg granules, 30mg granules and 100mg capsules were granted a UK marketing authorization in September 2011 with no requirement for an inclusion of a black triangle.

Abbott began to market Hidrasec in October 2012. All Hidrasec materials were sent to the MHRA for pre-vetting prior to the launch of the product. The MHRA did not request the addition of a black triangle. Abbott stated that it had no reason to suspect that Hidrasec would be a black triangle product as it had been licensed for over 10 years across Europe and the company had been informed by the MHRA to remove the black triangle from several of its other products as the black triangle scheme was to be phased out in anticipation of the new EU products for extensive monitoring list. Also the grant letter issued by the MHRA did not include any requirements for a black triangle to be added.

Therefore the materials used at this stage of the campaign were the pre-vetted MHRA materials and did not contain any black triangle warnings.

Abbott noted the complainant's reference to an advertisement from 'Guidelines' but as a copy had not been provided, the company could not comment on this advertisement.

Abbott first noticed that the MHRA had assigned a black triangle in the MHRA black triangle list – December 2012. Abbott immediately contacted the MHRA for clarification as it had not been informed of this and the list did not state that this was a new addition for that month. On 21 December the MHRA confirmed that Hidrasec had been added to the list but in error it was not flagged as a new edition. An urgent company communication was sent out to the field force (and head office) to quarantine all Hidrasec materials with clear instructions that materials should not be used (21 December). Agencies were also instructed to halt or remove any Hidrasec advertising.

On the first week of January Abbott was informed that the MHRA would review its decision. Abbott received a decision from the MHRA on 18 January that the black triangle would remain.

An immediate withdrawal and destruction of Hidrasec material was initiated. Materials had since been reprinted and recertified.

Journals were notified on 24 January 2013.

PANEL RULING

The Panel noted that the complainant had provided a copy of what appeared to be two advertisements. One featured a child kneeling and playing with a radio-controlled flying toy and another featured a child walking with a pull-along toy. It was not clear from these pages whether these were the advertisements published in Guidelines or not. They had website addresses. The Panel had no idea of the date of these advertisements.

Abbott stated that the complainant had not provided an advertisement. As the complainant was anonymous and non-contactable it was not possible to follow up on this.

The Panel noted that in correspondence with Abbott, the MHRA had stated that Hidrasec was added to the black triangle list in December 2012 when the agency became aware that the medicine was being marketed. The MHRA explained that products were only added to the black triangle list once the product was marketed and not when the marketing authorization was granted. The Panel noted, however, that the Hidrasec materials had been pre-vetted without any reference by the MHRA to the requirement to add a black triangle. Abbott had assumed that as Hidrasec had been available for over 10 years in Europe, it would not be subject to special reporting in relation to adverse reactions. The Panel noted Abbott's submission that once it was aware of the situation it had acted quickly to withdraw and destroy Hidrasec material without the triangle and reprint and issue new material.

The Panel noted that Clause 4.11 of the Code stated that when required by the licensing authority, all promotional material must show an inverted black triangle to denote that special reporting was required in relation to adverse reactions. It appeared that during the pre-vetting process,

the licensing authority had not told Abbott that a black triangle was required. The product was added to the black triangle list in December 2012 and Abbott had amended its materials in January 2013 when the decision was confirmed. The Panel noted that Hidrasec material had not displayed the black triangle symbol for three months or so. The Panel noted that if there was a date on the material provided by the complainant it could not be read. The Panel considered that taking all the circumstances into account the complainant had not proved his/her complaint on the balance of probabilities. In addition the product had not been placed on the black triangle list until 3 months after it was first marketed. The Panel thus ruled no breach of Clause 4.11.

3 Claim 'provides rapid control for even your smallest patients'

COMPLAINT

The complainant noted that as Hidrasec was only licensed for children over 3 months, Abbott could not claim that it 'provides rapid control for even your smallest patients'.

RESPONSE

Abbott noted that the claim at issue did not exist in isolation, but followed 'because it's licensed in infants older than 3 months' as shown below:

> 'Hidrasec specifically targets the uncontrolled secretory processes that underlie acute diarrhoea, reducing stool output and diarrhoea duration. **And because it's licensed in infants older than 3 months, Hidrasec, together with oral rehydration solution, provides rapid control for even your smallest patients'** (emphasis added).

Abbott submitted that Hidrasec was the only licensed anti-diarrhoeal in infants aged 3 months and above. Other anti-diarrhoeals were licensed for use in children aged 4 years and above. As the advertisement made it clear that the product was licensed from 3 months of age Abbott considered that this statement could be justified. Although Abbott acknowledged that MHRA pre-vetting of material did not equate to an automatic approval it noted that this advertisement had been pre-vetted by the MHRA and the statement was not disputed.

Abbott assured the complainant that it was committed to patient safety and strove to ensure appropriate messaging be aligned to its products.

PANEL RULING

The Panel noted that Section 4.1 of the Hidrasec summary of product characteristics (SPC) stated that the medicine was indicated, *inter alia*, for the complementary symptomatic treatment of acute diarrhea in infants aged over 3 months. The Panel noted that the claim at issue was preceded by the statement 'And because its licensed in infants older than 3 months...'. The Panel thus did not consider that the claim '...provides rapid control for even your smallest patients' was unacceptable as alleged; it was clearly within the context of infants older than 3 months and was thus not inconsistent with the particulars listed in the SPC. No breach of Clause 3.2 was ruled. The Panel did not consider that the claim was misleading; no breach of Clause 7.2 was ruled.

Complaint received **6 February 2013**

Case completed **17 April 2013**