CASE AUTH/2923/12/16

HOSPITAL PHARMACIST v MERCK SHARP & DOHME

Remicade advertisement

A hospital pharmacist, complained about a two page advertisement for Remicade (infliximab) issued by Merck Sharp & Dohme. The first page showed an illustration of an intact dandelion seed head beneath which was 'August 2016'. The claim '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide', referenced to data on file, also appeared together with the product logo which incorporated the strapline 'more than a name' which was also referenced to the data on file. Prescribing information was on page two.

The complainant stated that on first seeing the advertisement he/she was immediately drawn to the very large illustration of the blue sky and pollen flower and instantly inclined to believe that the medicine in question was licensed in allergy/ hay fever. This was not helped by the fact that 'Remicade' was in a particularly small font compared to that used elsewhere in the advertisement and as it was right at the bottom of the advertisement it could be missed by health professionals whereas the pollen illustration took up more than half of the page.

The complainant stated that this was particularly worrying as when he/she turned over the page for the prescribing information he/she saw that Remicade was not licensed for hay fever or allergy but for rheumatological conditions such as rheumatoid arthritis. The complainant noted that a spiral was depicted in the product logo and also in the centre of the pollen therefore further highlighting his/her point that Merck Sharp & Dohme had clearly linked the medicine to the pollen and thus implied that Remicade was licensed for conditions linked to pollen such as hay fever. The complainant alleged that this was misleading and might be taken as disguised promotion for an unlicensed indication.

The complainant stated that 'August 2016' was absolutely meaningless to any health professional; he/she did not understand what the date implied or what it had to do with Remicade by simply looking at the advertisement. Also as noted above, 'Remicade' was in small font at the end of the advertisement and so could be missed and thus the advertisement came across as pointless.

The complainant further alleged that the claim '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' was meaningless to health professionals as again it appeared like the 'August 2016' statement much larger (the Code stated that extremes of format and size should be avoided). Both of these statements appeared before the name of the medicine and so came across as meaningless and could lead to confusion especially if the medicine name was missed.

The complainant noted the strapline 'more than a name' was incorporated into the product logo and alleged that this was quite clearly a hanging comparison/exaggeration and there was no explanation/substantiation on why Remicade provided 'more' (more could be interpreted as a superlative under the Code).

Overall the complainant alleged that the advertisement was misleading, disguised promotion for an unlicensed indication and implied that Remicade was superior in some way without substantiation. The complainant alleged that high standards had not been maintained at all times and as such this had reduced his/her confidence in the pharmaceutical industry.

The detailed response from Merck Sharp & Dohme is given below.

The Panel noted that children often blew away the seeds of a dandelion clock in a game to find out what time it was. In that sense, a dandelion clock was used to measure the passage of time as in hours on a clock and not the passage of time as in years. The Panel thus did not consider that there was a clear connection between the picture of a dandelion clock and the claim regarding 17 years of clinical experience as submitted by Merck Sharp & Dohme. Nor did the Panel consider that it would be obvious to readers that the spiral in the middle of the dandelion clock, replicated in the product logo, represented the passage of time.

Despite the prominent depiction of the dandelion clock, the Panel did not consider that the advertisement promoted Remicade for allergy/ hay fever. The product logo, although in slightly smaller font than the claim about 17 years' clinical experience, was printed in bold type and in that regard the Panel did not consider that it would be easily missed as alleged. The advertisement had appeared in a health professional journal; readers would be aware that Remicade (infliximab) was a monoclonal antibody and so would be unlikely to think that it could be used for allergy/hay fever. There was no text in the advertisement to suggest such a use. The depiction of the dandelion clock did not, in and of itself, suggest that Remicade could be used for allergy/hay fever. No breach of the Code was ruled. This ruling was upheld on appeal by the complainant. In the Panel's view, the creative part of the advertisement did not promote Remicade for any indication at all. The prescribing information was printed overleaf and so in that regard the Panel considered that the advertisement promoted the rational use of Remicade. No breach of the Code was ruled. This ruling was appealed by the complainant.

The Panel noted the complainant's allegation with regard to the font size used in the advertisement.

In the Panel's view, the extremes of format or size referred to in the cited clause referred to the physical size of materials, not of the font size used within them. In that regard the Panel ruled no breach of the Code.

The Panel noted the allegation that the strapline, 'more than a name', in the product logo was misleading and implied some special merit. In the Panel's view it was not obvious what 'more than a name' was meant to convey; it did not agree with Merck Sharp & Dohme's submission that it was a simple statement of fact that Remicade was a branded prescription only medicine. Nor did it agree with the complainant's view that 'more than a name' was a hanging comparison. Overall the Panel considered that the strapline conveyed very little about Remicade and in that regard it was not misleading. No breach of the Code was ruled. This ruling was appealed by the complainant. The Panel also did not consider that the strapline was a superlative or that it implied some special merit. No breach of the Code was ruled. This ruling was appealed by the complainant.

The Panel noted its comments and rulings above and considered that high standards had been maintained. No breach of the Code was ruled which was upheld on appeal from the complainant. It thus followed that there had been no breach of Clause 2 and so the Panel ruled accordingly.

The Appeal Board noted that the advertisement at issue contained the statement '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' and the strapline 'more than a name' which were referenced to Merck Sharp & Dohme's data on file (PSUR). The data on file consisted of just over two lines of text (derived from the full PSUR) which noted that the latest global commercial exposure figure for Remicade, from its launch in 1998 to August 2015 was 2,437,109. The Appeal Board noted that the content of data on file was decided by the company.

The Appeal Board did not consider that, as submitted by Merck Sharp & Dohme the strapline simply drew attention to the brand and its anniversary. In the Appeal Board's view it implied that Remicade was more than its constituent, infliximab, because, *inter alia*, it had 17 years of clinical data and thereby implied a special merit versus other infliximabs. The Appeal Board considered that this implied a special merit for Remicade which was not substantiated by the data on file. No efficacy or safety data had been provided. The Appeal Board ruled a breach of the Code. The appeal on this point was successful.

Further the Appeal Board considered that the claim 'more than a name' was ambiguous and the claim and the referenced data on file were not sufficiently complete to allow the reader to form their own opinion on the therapeutic value of the medicine. A breach of the Code was ruled. The appeal on this point was successful.

The Appeal Board noted its rulings of breaches of the Code. Notwithstanding the fact that the advertisement included the prescribing information for Remicade overleaf, the Appeal Board considered that in addition the advertisement failed to promote the rational use of Remicade. It exaggerated the properties of Remicade and failed to present it objectively. The Appeal Board ruled a breach of the Code. The appeal on this point was successful.

A hospital pharmacist, complained about a two page advertisement for Remicade (infliximab) (ref RHEU-1191218-0001) issued by Merck Sharp & Dohme Limited and published in The Pharmaceutical Journal between October and December 2016.

The first page of the advertisement showed an illustration of an intact dandelion seed head beneath which was 'August 2016'. The claim '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide', referenced to data on file, also appeared together with the product logo which incorporated the strapline 'more than a name' which was also referenced to the data on file. Prescribing information was on page two.

Remicade was indicated for various conditions including rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

COMPLAINT

The complainant stated that Merck Sharp & Dohme had not operated in a responsible, ethical and professional manner with regard to the advertisement.

The complainant stated that on first seeing the advertisement he/she was immediately drawn to the very large illustration of the blue sky and pollen flower and instantly inclined to believe that the medicine in question was licensed in allergy/hay fever. This was not helped by the fact that 'Remicade' was in a particularly small font compared to that used elsewhere in the advertisement and as it was right at the bottom of the advertisement it could be missed by health professionals whereas the pollen illustration took up more than half of the page.

The complainant stated that this was particularly worrying as when he/she turned over the page for the prescribing information he/she saw that Remicade was not licensed for hay fever or allergy but for rheumatological conditions such as rheumatoid arthritis. The complainant noted that a spiral was depicted in the product logo and also in the centre of the pollen therefore further highlighting his/her point that Merck Sharp & Dohme had clearly linked the medicine to the pollen and thus implied that Remicade was licensed for conditions linked to pollen such as hay fever. The complainant alleged that this was particularly misleading and might be taken as disguised promotion for an unlicensed indication. Therefore, breaches of Clause 3 (in particular 3.2) and Clause 7.8 were alleged.

The complainant stated that 'August 2016' was absolutely meaningless to any health professional; he/she did not understand what the date implied or what it had to do with Remicade by simply looking at the advertisement. Also as noted above, 'Remicade' was in small font at the end of the advertisement and so could be missed and thus the advertisement came across as pointless.

The complainant further alleged that the claim '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' was meaningless to health professionals as again it appeared like the 'August 2016' statement much larger (the Code stated in Clause 9.7 to avoid extremes of format and size). Both of these statements appeared before the name of the medicine and so came across as meaningless and could lead to confusion especially if the medicine name was missed.

The complainant noted the strapline 'more than a name' incorporated into the product logo and alleged that this was quite clearly a hanging comparison/ exaggeration and there was no explanation/ substantiation on why Remicade provided 'more' (more could be interpreted as a superlative under Clause 7.10). The complainant thus alleged a breach of Clause 7 as Clause 7.10 stated that claims should not imply that a medicine or an active ingredient had some special merit, quality or property unless this could be substantiated and Clause 7.2 required that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly; claims must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Overall the complainant submitted that the advertisement was misleading, disguised promotion for an unlicensed indication and implied that Remicade was superior in some way without substantiation. The complainant alleged breaches of Clauses 9 and 2 as high standards had not been maintained at all times and as such this had reduced his/her confidence in the pharmaceutical industry.

In writing to Merck Sharp and Dohme the Authority asked it to bear in mind the requirements of Clauses 2, 3.2, 7.2, 7.8, 7.10, 9.1 and 9.7 of the Code.

RESPONSE

Merck Sharp & Dohme stated that it took compliance with the Code extremely seriously and acknowledged the high standards required for the promotion of medicines.

Merck Sharp & Dohme submitted that when the advertisement was published, Remicade had been on the market for 17 years as a 100mg powder for concentrate for solution for infusion. Treatment had to be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of rheumatoid arthritis, inflammatory bowel diseases, ankylosing spondylitis, psoriatic arthritis or psoriasis. Remicade should be administered intravenously.

The artwork in the advertisement was of a 'dandelion clock', well recognised in Britain as a symbolic measure of the passage of time. The Oxford Living Dictionary defined a dandelion clock as 'the downy, spherical seed head of a dandelion. Origin: From the child's game of blowing away the seeds to find out what time it is'. The date 'August 2016', cited in the advertisement represented the 17 year anniversary of the granting of the first marketing authorization for Remicade in August 1999.

The claim '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' was a factual statement about the number of years that Remicade had been available, and the number of patients treated.

This advertisement was intended to remind health professionals that after 17 years, Remicade was still available and still had therapeutic value for appropriate patients.

Prescribing information was provided as required by the Code and provided important information (including indications, dosage, precautions and warnings, and contraindications) for health professionals before they prescribed the medicine. In addition, the prescribing information clearly advised prescribers to 'Refer to Summary of Product Characteristics (SmPC) before prescribing'. The Remicade logo incorporated the strapline 'more than a name'. In summary the overall artwork and wording was to highlight to health professionals that Remicade was still a therapeutic option for appropriate patients, when prescribed in accordance to the prescribing information.

The artwork of a 'dandelion clock' did not refer, either directly or indirectly, to pollen, allergy or hay fever. It was there to provide a commonly recognised symbol of time. Whilst a dandelion seed head contained single seeded fruits and no pollen, Merck Sharp & Dohme noted that the artwork did not illustrate seed dispersal which further re-enforced Merck Sharp & Dohme's assertion that the artwork was far removed from the concept of allergy or hay fever associated with the spread of pollen. It was there to represent a symbol of time and the 'dandelion clock' was a commonly accepted and understood representation of time in British culture. Biologically the dandelion clock was not pollen itself nor did it contain pollen and it did not resemble pollen as the seeds were too large to be routinely inhaled by hay fever sufferers and cause symptoms. Additionally, there was no spreading of pollen to indicate that the artwork was related to allergy or hay fever. There was also no attempt to represent the symptoms, pathology or anatomy associated with hay fever and allergy.

The swirl ('spiral') alongside Remicade was also used within the dandelion, as part of the dandelion clock to represent the passage of time; Merck Sharp & Dohme did not believe that the swirl could be linked to pollen, hay fever or allergy.

Merck Sharp & Dohme confirmed that it was not involved in any research regarding the use of Remicade in allergy or hay fever. Nor was it aware

of any independently sponsored research regarding the use of Remicade in hay fever or allergy. Merck Sharp & Dohme was not seeking any form of licence for either of these disease areas and was also not aware of any published case reports of the use of infliximab in the treatment of allergy or hay fever. In summary, Merck Sharp & Dohme disputed that the advertisement promoted Remicade for indications (ie allergy, hay fever or otherwise) not covered by the marketing authorization (Clause 3.2) or that the artwork misled as to the nature of the medicine (Clause 7.8, supplementary information). The artwork/imagery was not a claim *per se*.

As discussed, above the date 'August 2016' together with the 'dandelion clock' represented the passage of time and 17 years of clinical experience with Remicade. Clause 9.7 stated that extremes of format and size must be avoided. The advertisement was A4 in size and would be viewed by the recipient as a whole page. Merck Sharp & Dohme disagreed that within the context of an A4 advertisement the size of the artwork or the font size of either the claim or the date were of extreme format or size, and thus it denied a breach of Clause 9.7. Merck Sharp & Dohme also maintained that due to the orderly format of the advertisement with simple artwork and very little text, the brand name Remicade with the generic name, infliximab, directly below, was of sufficient size to identify the medicine in question.

Merck Sharp & Dohme submitted that after reading the August 2016 date, the eye was immediately drawn to the adjacent text situated below which read '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide'; clearly linking August 2016 with the passage of 17 years, during which time over 2.4 million patients had been treated with Remicade. Merck Sharp & Dohme disagreed with the complainant's view that the text was meaningless, or that the date and statement could not be understood to be linked. Again, Merck Sharp & Dohme reiterated that the advertisement was A4 in size and would be viewed by the recipient as a whole page.

Merck Sharp & Dohme submitted that 'more than a name' was not a comparative or exaggerated claim. "More than a name" was a simple statement of fact that Remicade was a branded prescription only medicine. It was a statement that linked in with the overall impression of the advertisement and reminded health professionals that Remicade had 17 years of clinical experience and had therapeutic value for appropriate patients. Clause 7.10 stated that promotion should encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. The supplementary information stated that superlatives were those grammatical expressions which denoted the highest quality or degree, such as best, strongest, widest etc. Merck Sharp & Dohme did not believe that the inclusion of this statement either exaggerated the properties of Remicade, nor was a superlative as defined by the supplementary information to Clause 7.10. Merck Sharp & Dohme also submitted that 'more than a name' was not a 'hanging comparison' (Clause 7.2) as the statement did not present any property of the medicine favourably in relation to an unqualified comparator.

In summary, Merck Sharp & Dohme submitted that the advertisement was in accordance with the Code and did not breach Clauses 3.2, 7.2, 7.8, 7.10, or 9.7. Hence Merck Sharp & Dohme contended that high standards had been maintained (Clause 9.1) respecting the special status of medicines, and it had operated in a transparent, responsible, ethical and professional manner. Merck Sharp & Dohme submitted that it had not brought discredit to, or reduced confidence in, the industry (Clause 2).

PANEL RULING

The Panel noted that children often blew away the seeds of a dandelion clock in a game to find out what time it was. In that sense, a dandelion clock was used to measure the passage of time as in hours on a clock and not the passage of time as in years. The Panel thus did not consider that there was a clear connection between the picture of a dandelion clock and the claim regarding 17 years of clinical experience as submitted by Merck Sharp & Dohme. Nor did the Panel consider that it would be obvious to readers that the spiral in the middle of the dandelion clock, replicated in the product logo, represented the passage of time.

Despite the prominent depiction of the dandelion clock, the Panel did not consider that the advertisement clearly promoted Remicade for allergy/hay fever. The product logo, although in slightly smaller font than the claim about 17 years' clinical experience, was printed in bold type and in that regard the Panel did not consider that it would be easily missed as alleged. The advertisement had appeared in a health professional journal; readers would be aware that Remicade (infliximab) was a monoclonal antibody and so would be unlikely to think that it could be used for allergy/hay fever. There was no text in the advertisement to suggest such a use. No breach of Clause 3.2 was ruled. This ruling was not appealed. In the Panel's view, the depiction of a dandelion clock did not, in and of itself, suggest that Remicade could be used for allergy/hay fever. No breach of Clause 7.8 was ruled. This ruling was appealed by the complainant. In the Panel's view, the creative part of the advertisement did not promote Remicade for any indication at all. The prescribing information was printed overleaf and so in that regard the Panel considered that the advertisement promoted the rational use of Remicade. No breach of Clause 7.10 was ruled. This ruling was appealed by the complainant.

The Panel noted the complainant's allegation of a breach of Clause 9.7 with regard to the font size used in the advertisement. In the Panel's view, the extremes of format or size referred to in Clause 9.7 referred to the physical size of materials, not of the font size used within them. In that regard the Panel ruled no breach of Clause 9.7. This ruling was not appealed.

The Panel noted the allegation that the strapline, 'more than a name', in the product logo was

misleading and implied some special merit. In the Panel's view it was not obvious what 'more than a name' was meant to convey; it did not agree with Merck Sharp & Dohme's submission that it was a simple statement of fact that Remicade was a branded prescription only medicine. Nor did it agree with the complainant's view that 'more than a name' was a hanging comparison. Overall the Panel considered that the strapline conveyed very little about Remicade and in that regard it was not misleading. No breach of Clause 7.2 was ruled. This ruling was appealed by the complainant. The Panel also did not consider that the strapline was a superlative or that it implied some special merit. No breach of Clause 7.10 was ruled. This ruling was appealed by the complainant.

The Panel noted its comments and rulings above and considered that high standards had been maintained. No breach of Clause 9.1 was ruled. This ruling was appealed by the complainant. It thus followed that there had been no breach of Clause 2 and so the Panel ruled accordingly.

APPEAL BY THE COMPLAINANT

The complainant stated that after reading the response from Merck Sharp & Dohme and the Panel ruling he/she still considered the advertisement to be misleading and not within the spirit of the Code.

The complainant noted Merck Sharp & Dohme's in-depth knowledge on the 'dandelion clock' but stated that Merck Sharp & Dohme was confused by its analogy stating in its response that the 'dandelion clock' was '… blowing away the seeds to find out what time it is', this was obviously referring to the time in hours, not the number of years a medicine had been licensed for. Therefore, this illustration was inappropriate for this Remicade advertisement.

The complainant alleged that Merck Sharp & Dohme had assumed that readers of The Pharmaceutical Journal would simply look at the dandelion clock and instantly link the 17 year anniversary to it, however as stated above the illustration had no correlation to this anniversary. Merck Sharp & Dohme clearly seemed to be confused by the meaning behind the dandelion clock however, it expected health professionals reading The Pharmaceutical Journal to simply know what they were referring to. The readers of The Pharmaceutical Journal were medical professionals not plant/seed/flower/history experts and had varying roles within the pharmacy (retired, recently graduated, pharmacists, technicians, pre-registration, students) and also from different sectors ie hospital, community, academia, industry. The complainant as a pharmacist had never heard of the dandelion clock until reading Merck Sharp & Dohme's response.

The complainant alleged that Merck Sharp & Dohme seemed to contradict itself, on one hand it stated that the illustration of this dandelion clock did not include any spreading of the pollen/seeds. However, by using this dandelion clock and linking it to Remicade then there would certainly be seed dispersal as stated in its response the dandelion clock referred to '… blowing away the seeds to find out what time it is'.

The complainant alleged that the strapline 'more than a name' was cited by a reference which according to the advertisement was Merck Sharp & Dohme's data on file periodic safety update report (PSUR). The complainant was interested to see how this data actually substantiated the vague strapline/claim 'more than a name'. Merck Sharp & Dohme stated that the strapline showed Remicade was a branded prescription only medicine. The complainant was not sure why Remicade was any different from any other prescription-only medicine in that sense then, and why the strap line alluded to the fact that it provided more than just a name, surely this would be the case for any medicine! Therefore it could be argued that this strap line was indirectly exaggerating/promoting the benefits of Remicade without providing any further information.

The complainant stated that it was important to remember that not every reader of The Pharmaceutical Journal would have had experience dispensing, prescribing Remicade (infliximab) and as mentioned above the audience reading The Pharmaceutical Journal was wide. The complainant alleged that Merck Sharp & Dohme had produced an advertisement in which it had used an illustration which had nothing to do with its product and a strap line which again had no real meaning. As a reader of The Pharmaceutical Journal the complainant expected to see relevant, easy to understand and good quality advertisements, as health professionals did not have hours in their day to look at the hidden messages behind such advertisements from pharmaceutical companies or to google things like the dandelion clock. The complainant expected to understand exactly what was going on by looking at an advertisement straight away, this was not the case for this advertisement.

The complainant stated that the Code was in place to provide health professionals with confidence in the pharmaceutical industry. The materials Merck Sharp & Dohme produced needed to be relevant and clear to understand which had not been the case on this occasion. The complainant urged the Appeal Board to rule a breach of the Code as otherwise the case would set a precedent for other companies to use illustrations and straplines that had no correlation to the medicine they were advertising in professional health journals. This would lead to poor quality advertising which was simply not acceptable.

RESPONSE FROM MERCK SHARP & DOHME

Merck Sharp & Dohme submitted that it took compliance with the Code extremely seriously and acknowledged the high standards required for the promotion of medicines. Merck Sharp & Dohme submitted that the advertisement was in accordance with requirements of the Code and still disputed the complainant's view that it was in breach of Clauses 7.2, 7.8, 7.10, and 9.1.

Before responding to the continued concerns raised by the complainant in his/her appeal Merck Sharp &

Dohme provided background to the rationale of the artwork and the statements within the advertisement.

Merck Sharp & Dohme submitted that at the time of the advertisement, Remicade (infliximab) had been available on the market for 17 years as a 100 mg powder for concentrate for solution for infusion. The artwork in the advertisement was of a downy spherical seed head of the common dandelion plant, commonly known as a 'dandelion clock'. This was well recognised in Britain as a symbolic measure of the passage of time, as referred to in the Oxford Living Dictionaries' definition of a Dandelion Clock: 'Noun, British: The downy spherical seed head of a dandelion. Origin: From the Childs game of blowing away the seeds to find out what time it is'. Thus the creative element of the artwork in the advertisement represented the passage of time. Within the artwork was the date 'August 2016' followed underneath by the statement '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide'. Merck Sharp & Dohme submitted that this date ('August 2016') represented the 17 year anniversary of the granting of the first marketing authorisation for Remicade (August 1999). The statement underneath was a factual statement about the number of years that Remicade had been available, and the number of patients treated.

Merck Sharp & Dohme submitted that the advertisement was intended as a reminder to health professionals that after 17 years, Remicade was still available and still had therapeutic value for appropriate patients. Although Merck Sharp & Dohme acknowledged that the advertisement might not be to the complainant's preference, it maintained that the advertisement was in accordance with requirements of the Code, and respected the special status of medicines.

The complainant's appeal stated that based on Merck Sharp & Dohme's response the 'dandelion clock' referred to time in hours and not years and the illustration was inappropriate for this Remicade advertisement.

In response to the original complaint concerning the Remicade advertisement, Merck Sharp & Dohme submitted that the artwork was of a downy spherical seed head of the common dandelion plant, commonly known as a 'dandelion clock'. This was well recognised in Britain as a symbolic measure of the passage of time. Thus the creative element of the artwork in the advertisement represented the passage of time. The statement following underneath '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' put this passage of time into context; the number of years that Remicade had been available and the number of patients treated.

Merck Sharp & Dohme submitted that the artwork did not mislead as to the nature of the medicine (Clause 7.8 [Supplementary Information]). This advertisement was intended as a reminder to health professionals that after 17 years, Remicade was still available and still had therapeutic value for appropriate patients.

Merck Sharp & Dohme suggested that if a health professional did not recognise or understand the 'dandelion clock' artwork and/or the date 'August 2016', they would still be able to read the statement underneath '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' and link this to the medicine, Remicade.

Merck Sharp & Dohme submitted that medical professionals would not need to be 'plant/seed/flower/history experts' to understand the advertisement. Prescribing information had been provided with this advertisement, as required by the Code, to provide important information (including indications, dosage, precautions and warnings, and contraindications) for health professionals before they prescribed this medication. It was also important to note that treatment was to be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of rheumatoid arthritis, inflammatory bowel diseases, ankylosing spondylitis, psoriatic arthritis or psoriasis. Remicade infusions should also be administered by qualified health professionals trained to detect any infusion related issues.

As previously stated, Merck Sharp & Dohme did not consider that 'more than a name' was an exaggerated claim. 'More than a name' was a simple statement of fact that Remicade was a branded prescription only medicine. It was a statement that linked in with the overall impression of the advertisement, reminding health professionals that Remicade had 17 years of clinical experience and had therapeutic value for appropriate patients. The reference substantiated the number of patients treated with Remicade worldwide and the number of years that it had been commercially available, thus, indicating the wealth of clinical experience that had been accrued over this time. Clause 7.10 stated that promotion should encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. The supplementary information stated that superlatives were those grammatical expressions which denoted the highest quality or degree, such as best, strongest, widest etc. Merck Sharp & Dohme submitted that the inclusion of this statement neither exaggerated the properties of Remicade, nor was a superlative as defined by the supplementary information to Clause 7.10. Merck Sharp & Dohme also submitted that 'more than a name' could not be interpreted as a 'hanging comparison' (Clause 7.2) as the statement did not present any property of the medicine favourably in relation to an un-qualified comparator.

In summary Merck Sharp & Dohme submitted that this advertisement was not in breach of Clauses 7.2, 7.8, and 7.10. Hence Merck Sharp & Dohme submitted that high standards had been maintained (Clause 9.1) respecting the special status of medicines, and it had operated in a transparent, responsible, ethical and professional manner.

FINAL COMMENTS FROM THE COMPLAINANT

There were no final comments from the complainant.

APPEAL BOARD RULING

The Appeal Board noted that the advertisement at issue contained the statement '17 years of Clinical Experience with over 2.4 Million Patients treated worldwide' and the strapline 'more than a name' which were referenced to Merck Sharp & Dohme's data on file (PSUR). The data on file consisted of just over two lines of text (derived from the full PSUR) which noted that the latest global commercial exposure figure for Remicade, from its launch in 1998 to August 2015 was 2,437,109. The Appeal Board noted that the content of data on file was decided by the company.

The Appeal Board did not consider that, as submitted by Merck Sharp & Dohme in the context of the advertisement the strapline simply drew attention to the brand and its anniversary. In the Appeal Board's view it implied that Remicade was more than its constituent, infliximab, because, *inter alia*, it had 17 years of clinical data and thereby implied a special merit versus other infliximabs. The Appeal Board considered that this implied a special merit for Remicade which was not substantiated by the data on file. No efficacy or safety data had been provided. The Appeal Board ruled a breach of Clause 7.10. The appeal on this point was successful.

Further the Appeal Board considered that the claim 'more than a name' was ambiguous and the claim and the referenced data on file were not sufficiently complete to allow the reader to form their own opinion on the therapeutic value of the medicine. A breach of Clause 7.2 was ruled. The appeal on this point was successful.

The Appeal Board considered that the depiction of a dandelion clock, in and of itself, did not suggest that Remicade could be used for allergy/hay fever. The Appeal Board upheld the Panel's ruling of no breach of Clause 7.8. The appeal on this point was unsuccessful.

The Appeal Board did not consider in the circumstances that high standards had not been maintained and it upheld the Panel's ruling of no breach of Clause 9.1. The appeal on this point was unsuccessful.

During the preparation of the case report in the above case it was noted that the Appeal Board had not ruled on the complainant's appeal of the Panel's ruling of no breach of Clause 7.10 in relation to whether the advertisement promoted the rational use of Remicade. The Chairman apologised for this regrettable oversight and decided that the appeal of no breach of Clause 7.10 should be considered.

The Appeal Board noted that Clause 7.10 stated that promotion must encourage the rational use of a medicine by presenting it objectively and not exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they related to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient had some special merit, quality or property unless this could be substantiated.

The Appeal Board noted its comments and rulings of breaches of the Code above including that the strapline 'more than a name' implied a special merit for Remicade which was not substantiated by the data on file (Clause 7.10) and that the claim was ambiguous (Clause 7.2). Notwithstanding the fact that the advertisement included the prescribing information for Remicade overleaf, the Appeal Board considered that given these comments and rulings and the wording of Clause 7.10, it followed that the advertisement in addition, failed to promote the rational use of Remicade. It exaggerated the properties of Remicade and failed to present it objectively. The Appeal Board ruled a breach of Clause 7.10. The appeal on this point was successful. The Appeal Board considered that this ruling of a breach of Clause 7.10 did not impact on its ruling of no breach of Clause 9.1 of the Code.

Complaint received **20 December 2016**

Case completed **7 August 2017**