CASE AUTH/2432/8/11

NAPP v GRÜNENTHAL

Promotion of Palexia

Napp complained about two claims in a Palexia SR (tapentadol prolonged release) leavepiece issued by Grünenthal. Palexia SR was indicated for the treatment of severe chronic pain in adults which could be managed only with opioid analgesics.

The detailed response from Grünenthal is given below.

The claim 'Introducing a new class in pain relief' was referenced to Kress (2010). Napp stated that tapentadol was an agonist at the μ-opioid receptor (MOR) (like other opioids) and also had inhibitory activity at the noradrenaline receptor (noradrenaline reuptake inhibition (NRI)) (like tramadol), and Napp did not consider that the receptor activity warranted the description 'a new class'. In addition, the anatomical therapeutic chemical (ATC) classification system grouped tapentadol with other opioids. Kress published a round table discussion 'Tapentadol and its two mechanisms of action; Is there a new pharmacological class of centrally-acting analgesics on the horizon?'. This group, a small number of European clinicians assembled by Grünenthal, concluded by merely questioning whether tapentadol should be considered a new class of medicine. Napp alleged that the claim was exaggerated and could not be substantiated.

The Panel noted that, although in the same ATC class, there were pharmacological differences between tapentadol and tramadol. It further noted Grünenthal's submission that as tapentadol was the only molecule with a MOR-NRI mode of action it was unlikely that a new ATC class would be created as this only usually occurred when there were at least two members of the group.

The Panel noted that the Palexia summary of product characteristics (SPC) stated that the medicine's pharmacotherapeutic group was 'Analgesics; opioids; other opioids'. The Panel thus did not accept that Palexia was a new class in pain relief and ruled that the claim was misleading in breach of the Code. Further, the Panel did not consider that the claim could be substantiated. The proposal that tapentadol was a new class of medicine was from a company-funded discussion group and had not been formally accepted by the wider medical community. In any event the Palexia SPC did not state a new drug class for the medicine. A breach of the Code was ruled.

Napp alleged that the three studies, on which the claim '…superior gastrointestinal tolerability' compared with oxycodone was based, were not powered for tolerability endpoints. Below the claim was a bar chart which compared the incidence of TEAEs (treatment-emergent adverse events) for Palexia SR and oxycodone CR in relation to constipation, nausea, vomiting, dry mouth and diarrhoea and a composite of nausea and vomiting. The differences were in favour of Palexia for constipation, nausea, vomiting and nausea and vomiting ($p<0.001$). The claim 'superior tolerability' was based on TEAEs which Napp submitted were any spontaneously reported adverse events occurring after the start of study medicine. Spontaneously reported adverse events gave less reliable results than specific measures designed to pro-actively seek out specific side effects. The severity of the TEAEs was not stated which Napp considered could significantly affect interpretation of the results and therefore a clinician's benefit/risk assessment of tapentadol compared with oxycodone. Similarly, the relationship of the TEAE to the study medicine was not reported. Napp alleged that this superlative claim misled by exaggeration, and could not be substantiated.

The Panel noted that the claim at issue and the bar chart were based on Lange *et al* (2010), a meta-analysis of pooled data from three studies. Each of the studies had actively collected adverse events. Napp was incorrect to imply that the claim was based only on spontaneously reported adverse events occurring after the start of the study medicine. The Panel noted that the three studies consistently showed that tapentadol had better gastrointestinal tolerability compared with oxycodone.

The Panel considered that given that the three source studies had actively collected adverse event data and that the data for constipation, nausea, vomiting and nausea and vomiting, was consistent across all three studies (and statistically significantly in favour of tapentadol) then the claim for superior gastrointestinal tolerability based on the pooled analysis by Lange *et al* was not misleading and could be substantiated. The Panel did not consider that the claim was exaggerated and nor was it a superlative. No breach of the Code was ruled.

Napp Pharmaceuticals Limited complained about two claims in a 6 page, gate-folded leavepiece (ref P10 0140) used by Grünenthal Ltd to promote Palexia SR (tapentadol prolonged release). Palexia SR was indicated for the treatment of severe chronic pain in adults which could be adequately

managed only with opioid analgesics. Napp marketed Oxycontin (oxycodone) which was indicated for moderate to severe cancer pain, post-operative pain or severe pain requiring a strong opioid.

1 Claim 'Introducing a new class in pain relief'

This claim appeared in a highlighted box at the top of page 1 of the leavepiece; it was referenced to Kress (2010).

COMPLAINT

Napp stated that tapentadol was an agonist at the μ-opioid receptor (MOR) (like morphine, oxycodone and other opioids) and also had noradrenaline reuptake inhibition (NRI) activity (like tramadol). These two mechanisms, responsible for the analgesia of tapentadol, were both found in tramadol and thus Napp did not consider that the receptor activity, and the similarity to tramadol, warranted the description 'a new class'. In addition, the anatomical therapeutic chemical (ATC) classification system grouped tapentadol with other opioids; the difference in coding related only to tapentadol being a different chemical substance within the same group, N02AX – other opioids.

Kress had published the results of a round table discussion entitled 'Tapentadol and its two mechanisms of action; Is there a new pharmacological class of centrally-acting analgesics on the horizon?'. Napp stated that the question mark at the end of the title clearly indicated that this was at discussion level only rather than acceptance. This group (a small number of European clinicians) was assembled by Grünenthal to debate the issues around class. The conclusion merely questioned whether tapentadol should be considered a new class of medicine, rather than firmly suggesting that it should be. However, it was unlikely that a small group of clinicians operating within an activity entirely funded by Grünenthal had sufficient independence or influence to dictate that tapentadol could be considered to be a new class. Indeed, Kress only suggested that a new class for tapentadol could be proposed. However, Napp believed that even the statement suggested by Grünenthal during inter-company dialogue, 'a proposed new class' did not represent the balance of independent (non-Grünenthal funded) evidence.

Napp alleged that the claim was exaggerated in breach of Clause 7.2 and could not be substantiated in breach of Clause 7.4.

RESPONSE

Grünenthal stated that whilst both tramadol and tapentadol had MOR agonist and NRI activity there were many differences between the two which would differentiate them into separate classes. The main difference between the medicines was that tramadol, in addition to MOR activation and NRI activity, combined a third mechanism of action ie inhibition of serotonin reuptake. *In vitro* and *in vivo* studies indicated that tapentadol had no relevant serotonin activity (Tzschentke *et al* 2007 and Schroder *et al* 2010). Serotonin, in contrast to noradrenaline, was also a transmitter in the descending excitatory pathway. As a result serotonin could have both an anti-nociceptive effect and a pro-nociceptive effect (Bannister *et al* 2009 and Suzuki *et al* 2004), thus questioning the value of this mechanism for reliable analgesic effects. This view was supported by the observation that generally selective serotonin reuptake inhibitors (SSRIs) had only small and inconsistent analgesic effects (Mico *et al* 2006).

Grünenthal submitted that another major difference between the two medicines was that tapentadol existed as a single enantiomer (non-racemic) (Tzschentke *et al*) while tramadol and its active M1 metabolite both existed as racemates (Grond and Sablotzki 2004). The NRI and serotonin reuptake inhibition activity of tramadol mainly resided in the (–) and (+)-enantiomer of the parent compound, respectively, whereas MOR activation resided in the (+)-enantiomer of O-desmethyl-tramadol (M1 metabolite), and to a lesser degree in (+)-tramadol itself. Thus, whereas tapentadol exerted its analgesic effects without the need for metabolic activation, with both mechanisms of action present in a constant ratio, tramadol was a pro-drug and required metabolism to achieve its main MOR activity.

The two medicines were also metabolised in very different ways. Tapentadol mainly via glucuronidation, without prior oxidation via CYP450, and so there was low potential for drug-drug interactions. Tramadol was metabolised mainly by N- and O-demethylation (N-demethylation mediated by CYP3A4 and CYP2B6 and O-demethylation mediated by CYP2D6) and glucuronidation or sulfation in the liver (Grond and Sablotzki).

Grünenthal noted Napp's submission that the ATC classification of tapentadol gave further evidence that it was not a new class of pain relief. Grünenthal submitted that the ATC classification was not always an appropriate way to define a new class for innovative new chemical entities such as tapentadol. Indeed, the ATC code website stated that '… the ATC system is not strictly a therapeutic classification system'. In the ATC system medicines were classified according to the main therapeutic use of the main active ingredient. Tapentadol had two modes of action, MOR and NRI, in a single molecule, based on preclinical data neither MOR nor NRI could be classed as the 'main active ingredient'. It could also not be considered a combination product. Whereas medicines which worked on the opioid receptors were classified as analgesic opioids (N02A), NRIs were classified as antidepressants (N06A). Given that tapentadol worked as an analgesic, it was not unreasonable, given the limitations of the current classification system, for it to be categorised within the opioid

N02A group. Furthermore, as tapentadol was currently the only molecule with a MOR-NRI mode of action it was unlikely that a new class would be created. As stated on the ATC website 'Subdivision on the mechanism of action will, however, often be rather broad, since a too detailed classification according to mode of action often will result in having one substance per subgroup which as far as possible is avoided'. Within the N02A class subgroups were differentiated at the fourth level based on their chemical structure rather than their pharmacological activity. New analgesic compounds with any opiodergic mechanism of action were entered into an undifferentiated N02AX class. Creation of a new class would usually only occur when there were at least two members of the group. The ATC codes for tapentadol and tramadol were N02AX06 and N02A02 respectively. The fact that tapentadol and tramadol had not been classified together in a new group further differentiated the two. However, given that Grünenthal proposed that tapentadol was a member of new class of pain relief based on its pharmacological mechanism of action, MOR-NRI, differentiation based on chemical structure, as was the case within the N02A class, had less relevance than if differentiation was by pharmacological mechanism.

Based on the above rationale Grünenthal did not consider the claim that tapentadol represented a new class of pain relief was exaggerated and as such was not in breach of Clause 7.2.

With regard to Kress, 'Tapentadol and its two mechanisms of action; Is there a new pharmacological class of centrally-acting analgesics on the horizon?' used to substantiate the claim, Grünenthal submitted that the question mark struck the tone of the paper and provided a hypothesis to debate in the editorial. Given that the conclusion stated '… it seems reasonable to propose that with the new analgesic drug tapentadol a new class of centrally-acting analgesics, designated MOR-NRI, has appeared on stage', this reference fully substantiated the claim of a new class for tapentadol.

Grünenthal submitted that the expert panel brought together to debate the issue consisted of eleven clinicians and pharmacologists from across Europe and the US of international acclaim. Grünenthal stated that in its view eleven experts was a sufficient number to provide a fair and balanced opinion. Given their high standing the panel members would not advocate a position for tapentadol that might question their academic credibility or integrity. As such their view on a new class for tapentadol could be considered independent and authoritative.

Grünenthal submitted that Kress adequately substantiated the claim of a new class in pain relief for tapentadol, and therefore was not in breach of Clause 7.4.

PANEL RULING

The Panel noted that, although in the same ATC class, there were pharmacological differences between tapentadol and tramadol. However, the Panel further noted Grünenthal's submission that as tapentadol was the only molecule with a MORI-NRI mode of action it was unlikely that a new ATC class would be created. The company had further submitted that creation of a new ATC class would only usually occur when there were at least two members of the group.

The Panel noted that the Palexia SPC stated that the medicine's pharmacotherapeutic group was 'Analgesics; opioids; other opioids'. In that regard the Panel did not accept that Palexia was a new class in pain relief as stated in the claim at issue. The Panel thus considered that the claim was misleading as alleged. A breach of Clause 7.2 was ruled. Further, the Panel did not consider that the claim could be substantiated. Kress, upon which Grünenthal relied for substantiation, was the output of a round table conference convened by the company to discuss *inter alia* the pharmacological profile of tapentadol. The author stated that it seemed reasonable to *propose* that tapentadol was a new class of medicine, designated MOR-NRI. This was, however, only a proposal from a company-funded discussion group and had not been formally accepted by the wider medical community. In any event the Palexia SPC did not state a new drug class for the medicine. The Panel considered that the claim could not be substantiated as alleged. A breach of Clause 7.4 was ruled.

2 Claim '…superior gastrointestinal tolerability' compared with oxycodone

The middle section of the inside spread of the leavepiece was headed 'Palexia SR – Unlock the potential of potent analgesia and fewer side effects compared to oxycodone CR'. This was followed by a subheading 'Palexia SR: Comparable pain relief to oxycodone CR', a graph and then the claim at issue '… with superior gastrointestinal tolerability'. The claim was referenced to Lange *et al* (2010) which was a pooled analysis of data from three phase 3 studies. Below the claim was a bar chart which compared the incidence of TEAEs (treatment-emergent adverse events) for Palexia SR and oxycodone CR in relation to constipation, nausea, vomiting, dry mouth and diarrhoea and a composite of nausea and vomiting. The differences were in favour of Palexia for constipation, nausea, vomiting and nausea and vomiting ($p<0.001$). The bar chart was adapted from Lange *et al*.

COMPLAINT

Napp alleged that the three pivotal source studies on which the claim was based were not powered to look at tolerability endpoints; the only gastrointestinal (GI) tolerability-specific measure in the studies was the secondary endpoint of the

patient assessment of constipation symptoms (PAC-SYM) questionnaire, one of multiple secondary endpoints used in all three studies but not referred to in the leavepiece. The claim 'superior tolerability' was based on TEAEs which Napp submitted were any spontaneously reported adverse events occurring after the start of study medicine. Napp objected to the conclusion of superior tolerability drawn from adverse event reporting for several reasons. Firstly, spontaneously reported adverse events gave less reliable, and therefore less valid, results than specific measures designed to pro-actively seek out specific side effects. To substantiate a superlative claim required data from the accurate and proactive measuring of validated GI symptom-specific measures as primary endpoints (or secondary endpoints provided that the primary endpoint was met). The severity of the TEAEs was not stated in the leavepiece and this could significantly affect interpretation of the results and therefore a clinician's benefit/risk assessment of tapentadol compared with oxycodone. For example, both groups might experience nausea, but if, on average, this was mild in one group and severe in the other, this could significantly affect the clinician's decision making. Similarly, the relationship of the TEAE to the study medicine was not reported (or even raised to aid the accurate interpretation of the leavepiece). Although Grünenthal provided an assessment of relatedness in inter-company dialogue, Napp was concerned that a superlative claim was based on unpowered adverse event data.

Napp alleged that this superlative claim misled by exaggeration, was not substantiated by the data presented alongside the claim and remained unsubstantiated in breach of Clauses 7.2, 7.4 and 7.10.

RESPONSE

Grünenthal agreed that the three primary studies (Buynak *et al* 2010, Afilalo *et al* 2010 and data on file (from study NCT00486811)) were specifically powered to detect the primary efficacy endpoint, and not GI tolerability. However, GI safety and tolerability endpoints (constipation and nausea or vomiting adverse events and PAC-SYM) were pre-specified in all three studies. Furthermore, changes from baseline of the PAC-SYM subscales and overall scores were designated as secondary endpoints. The pre-specified analysis plan for the three studies stated 'the effect of tapentadol PR compared to oxycodone CR for adverse events of nausea, vomiting and constipation during the double-blind period will be investigated. The nausea and vomiting composite event rates will be tested as well as the individual constipation event rate'. Analysis of adverse events was a requirement in registration studies and as such was seldom stated as a specific end point.

Grünenthal submitted that in all studies tapentadol PR demonstrated significant improvements in GI tolerability (constipation and nausea and/or vomiting adverse events and PAC-SYM) compared with oxycodone CR. The studies showed significant differences in GI TEAEs between active groups; tapentadol PR patients were significantly less likely to experience constipation and nausea and/or vomiting than patients in the oxycodone CR group ($p<0.001$ for all studies). An additional post-hoc analysis, showed that overall GI tolerability was also significantly different favouring tapentadol PR over oxycodone CR. Grünenthal stated that this was new data.

For PAC-SYM, the mean changes from baseline at endpoint in the overall PAC-SYM score were statistically significantly lower in the tapentadol PR groups compared with the oxycodone CR groups in all three studies ($p \leq 0.02$) indicating more severe scores in the oxycodone CR group. The differences in the mean change from baseline in abdominal, rectal and stool subscales were also statistically significantly different (with the exception of the abdominal subscale in Buynak *et al*) in favour of tapentadol PR in the three studies. These findings were consistent with the lower percentage of subjects with TEAEs of constipation observed in the tapentadol PR groups compared with the oxycodone CR groups.

Whilst tolerability was not the primary endpoint across all three studies, Grünenthal submitted that it had consistently shown statistically and clinically meaningful differences demonstrating that tapentadol PR had an improved GI tolerability compared with oxycodone CR. Given the replication of these findings in three separate independent studies, the chance that this was due to an error (ie claiming a difference based on the three trials although there was none in reality) was unlikely. In fact, similar results with improved GI tolerability for tapentadol PR compared with oxycodone CR was seen in all studies, including a one year safety study (Wild *et al* 2010). As the comparisons in all three independent studies gave significant results, Grünenthal submitted that it was not relevant that the single trials were not powered for an adverse event comparison and no formal hypothesis testing was required to accept the difference between tapentadol PR and oxycodone CR. These studies therefore provided sufficient evidence to substantiate a claim of superior GI tolerability.

Moreover, unlike the three primary studies which were not specifically powered to detect differences in GI adverse events between the two active comparators, Grünenthal submitted that the pre-planned pooled-analysis allowed for a direct comparison between oxycodone CR and tapentadol PR. The pooled analysis was calculated as having more than 99% power to show GI superiority (based on previous trial data). Demonstration of superior GI tolerability was among the primary objectives of the pooled-analysis. The pre-specified pooling of these studies demonstrated a highly significant difference ($p<0.001$) in GI TEAEs between tapentadol PR and oxycodone CR favouring tapentadol PR as a primary endpoint (Lange *et al*).

Grünenthal submitted that Lange *et al* substantiated the claim of superior GI tolerability.

Further evidence to support the claim came from the lower discontinuation rates due to adverse events seen in the tapentadol PR group (18.3%) compared with the oxycodone CR group (39.4%) in the pooled analysis in Lange *et al*. Specific rates of discontinuation due to GI adverse events, were also lower in the tapentadol PR group (8.1%), compared with oxycodone CR (24.7%) (data on file). In addition oxycodone CR patients discontinued treatment significantly earlier than tapentadol PR patients (median time to discontinuation 39 days vs 118 days respectively p<0.001).

Grünenthal submitted that, based on the evidence presented above, there was no breach of Clause 7.2.

With respect to the use of TEAEs to support the claim of superior tolerability, Grünenthal considered that these reported adverse events gave reliable and valid results about specific side effects. Collecting unsolicited adverse event reports was standard in drug safety and the accepted industry standard for adverse drug reaction determination. The collection of reported adverse events could not be validated but this did not mean the results were unreliable. Within all studies, physicians continuously and proactively monitored adverse events by using non-leading questions at each study visit (weekly during titration; eight times throughout the 12 week maintenance period), and in follow-up telephone calls. These adverse events should not be considered spontaneously reported. Adverse events were also collected through spontaneous reports from patients. All trials were double-blind and randomised which helped to avoid biased adverse event reporting between the two active treatments. This was evidenced by the consistency of the adverse events results across the three independent trials. The trials also included large numbers of patients (pooled analysis: placebo n=993; tapentadol PR n=981; oxycodone CR n=1,001, Lange *et al*) which also limited any effect of biased reporting.

Grünenthal believed that a specific validated measure of GI symptoms was not necessarily required to demonstrate differences in GI tolerability. While GI adverse events might be less sensitive at detecting differences between adverse events between active groups, in studies (such as those detailed above) where clear differences in GI tolerability were observed between active groups, Grünenthal considered GI adverse events to be adequate evidence to substantiate a superlative claim of superior GI tolerability.

Regarding the severity of the TEAEs not being defined in the leavepiece and the concern that this could significantly affect interpretation of the results and therefore the clinician's benefit/risk assessment of tapentadol PR compared with oxycodone CR, Grünenthal submitted that whilst not reported by Lange *et al*, in all of Grünenthal's clinical trials the intensity of the adverse events was scored as follows: mild – signs and symptoms which could be easily tolerated, symptoms could be ignored and disappeared when the subject was distracted; moderate – symptoms which caused discomfort but were tolerable, they could not be ignored and affected concentration; severe – symptoms affected usual daily activity. A statistical analysis on the intensity of reported GI adverse events in the pooled analysis of the three trials, showed that the oxycodone CR group reported more severe GI adverse events than the tapentadol PR group (p=0.03). Grünenthal provided a copy of top level data it had provided to Napp to substantiate this during inter-company dialogue. Napp did not ask for further details. Given that the severity of the adverse events was less in the tapentadol PR group, the bar chart in the leavepiece showing just the proportions of the GI adverse events under the title '… with superior gastrointestinal tolerability [compared to oxycodone CR]' referenced to Lange *et al* did not affect the interpretation of the results or the clinician's benefit/risk assessment of tapentadol PR compared with oxycodone CR.

Grünenthal thus submitted that the claim of superior tolerability compared with oxycodone CR was accurate, balanced and represented a fair evaluation of all the evidence, and that the claim and the bar chart below it were not misleading or in breach of Clauses 7.2, 7.4 or 7.10.

Regarding Napp's view that the relationship of the TEAE to the study medicine was not reported, therefore adverse events unrelated to the study medicine could significantly bias the quoted TEAEs and mislead the clinicians about the profile of tapentadol compared with oxycodone, Grünenthal submitted that while the relationship between the study medicine and the TEAEs was not reported, overall the majority of GI adverse events were possibly, probably or certainly related to the study medicine. The proportions were similar between the two medicines (tapentadol PR, 89%; oxycodone, CR 91%) and for both medicines 98% of constipation was considered related to the study medicine. Analysis of GI TEAEs specifically associated with the study medicine showed that the tapentadol PR group had significantly less overall GI TEAEs, nausea, vomiting and constipation than oxycodone CR (data on file). Grünenthal had provided data to Napp to substantiate this and Napp did not ask for further details. Further details and statistical analysis of the data provided to Napp was provided. Given that the majority of adverse events were related to the two active study medicines and these results were consistent for both tapentadol PR and oxycodone CR, there was no reason to believe that this would significantly bias the interpretation of the quoted figures of TEAEs reported in the publications. Therefore, by presenting a bar chart showing just the proportions of the GI adverse events under the title '… with superior gastrointestinal tolerability (compared to oxycodone CR)' referenced to Lange *et al* Grünenthal had not misled clinicians about the

profile of tapentadol PR compared with oxycodone CR. Therefore Grünenthal submitted that the claim of superior tolerability compared with oxycodone CR was accurate, balanced and represented a fair evaluation of all the evidence, and that the claim and the bar chart below it were not misleading or in breach of Clauses 7.2, 7.4 or 7.10.

PANEL RULING

The Panel noted that the claim at issue and the bar chart were based on Lange *et al* which was a meta-analysis of pooled data from three studies (data on file (from study NCT00486811), Afilalo *et al* and Buynak *et al*). A total of 2,974 patients (placebo, n=993; tapentadol, n=980 and oxycodone, n=1,001) were evaluable for safety. Each of the three studies had actively collected adverse event data. In study NCT00486811 adverse events were continually monitored or asked about using a non-leading question at each visit and follow up telephone call. Adverse events reported spontaneously by patients were also documented. Afilalo *et al* monitored adverse events throughout the study and for 10-14 days after discontinuation of the study medicine and Buynak *et al* assessed safety throughout the study using, *inter alia*, adverse event reporting. All three studies also used the PAC-SYM questionnaire. In that regard the Panel considered that Napp was incorrect to imply that the claim was based only on spontaneously reported adverse events occurring after the start of the study medicine.

The Panel noted that the three studies consistently showed that tapentadol had better GI tolerability compared with oxycodone. The percentage incidence of the various side effects was also similar across the studies eg the percentage incidence of nausea for tapentadol was 20.38% (study NCT00486811), 21.5% (Afilalo *et al*) and 20.1% (Buynak *et al*); the pooled analysis (Lange *et al*) reported a figure of 20.7%. The corresponding figures for oxycodone were 37.16%, 36.5%, 34.5% and 36.2%.

The Panel considered that given that the three source studies had actively collected adverse event data and that the data for constipation, nausea, vomiting and nausea and vomiting, was consistent across all three studies (and statistically significantly in favour of tapentadol) then the claim for superior gastrointestinal tolerability based on the pooled analysis by Lange *et al* was not misleading. The pooled data showed no statistically significant difference between the two medicines with regard to incidence of dry mouth and diarrhoea. The Panel also noted that data had been provided which demonstrated that for individual GI TEAEs there was no statistically significant difference in the distribution of the severity of such events between tapentadol and oxycodone and that treatment discontinuations due to GI TEAEs occurred more often in the oxycodone group than in the tapentadol group. No breach of Clause 7.2 was ruled. The Panel considered that the claim could be substantiated and so it ruled no breach of Clause 7.4. The Panel did not consider that the claim was exaggerated and nor was it a superlative. No breach of Clause 7.10 was ruled.

Complaint received **16 August 2011**

Case completed **26 October 2011**