CASE AUTH/1974/3/07

ANONYMOUS EMPLOYEES v MERCK SHARP & DOHME

Provision of a service and representative call rates

An anonymous group of Merck Sharp & Dohme employees complained about the provision of a service by the company and representatives' call rates.

The complainants alleged that Merck Sharp & Dohme had misled the Authority in its appeal of the Panel's ruling of a breach of Clause 2 in relation to the conduct of the forearm DEXA placement initiative operated from 2002 to 2004 by the FROSST division of the Merck Sharp & Dohme sales force (Case AUTH/1859/6/06).

The complainants noted that in its appeal, Merck Sharp & Dohme had claimed that the 'DEXA placements DIY Guide' slide presentation was shared with a small group of representatives and not the entire FROSST sales division (approximately 60 representatives reporting to six regional managers with the first line sales responsibility for Fosamax promotion). This was untrue; the small group of representatives (six representatives and four sales managers) was the 'Fosamax Best Practice Team', which met two or three times each year to facilitate sharing of ideas (best practice) in relation to selling activities across the entire FROSST sales division.

According to both current and past members of the FROSST sales division the best practice team would 'cascade' ideas to each regional team. The slide presentation 'DEXA Placements DIY Guide' was one such example. The complainants now provided a copy of the generic objectives document for FROSST sales representatives for 2003 – the 'Performance Planning Form'. In relation to Merck Sharp & Dohme's denial of an intended link between DEXA placements and product promotion the complainants noted the sub-heading under Objective 1: 'Implementation of xxxx Market Expansion (e.g. DEXA placements) project placements ensuring an at least 40% diagnostic hit rate and at least 80% of all Osteoporotic patients identified are treated with Fosamax Once Weekly by December 2003'.

FROSST sales personnel based their personal objectives upon this generic template. However, as the complainants were not prepared to reveal their identity they could not provide named representatives' objective documents.

The complainants had obtained copies of two slides on the national overview of the DEXA programme used by the national sales management team in presentations to Merck Sharp & Dohme's UK senior management. Two slides were provided regarding the 2002 programme throughput up to May and the plan for 2003. These slides correlated with the target of 80% Fosamax usage amongst patients identified as osteoporotic as stated within the representatives' objectives document. This supported the complainants' original contention in Case AUTH/1859/6/06 that the new managing director for Merck Sharp & Dohme UK, who was business unit director for the musculoskeletal business unit responsible for the FROSST sales division, was aware of the conduct and linkage of product promotion to service to medicine of this initiative. The FROSST national sales manager from 2002 to 2004 was appointed to co-chair Merck Sharp & Dohme's compliance oversight committee formed in response to Case AUTH/1814/3/06. The complainants noted the potential conflict of interest given that the other co-chair of the compliance oversight committee was the business unit director responsible for the activities in question in Case AUTH/1814/3/6.

The Panel noted that, according to the complainants, the Best Practice Team (which Merck Sharp & Dohme had stated was a small number of representatives, managers and marketing specialists) to whom the 'DEXA Placements DIY Guide' was presented would share ideas in relation to selling activities across the entire FROSST sales division. At the appeal in Case AUTH/1859/6/06, although the Appeal Board had been alarmed at the document and concerned that anyone could have produced it, it had ruled that there was no evidence on the balance of probabilities that the document had been used to train representatives, had otherwise been disseminated beyond the meeting or had otherwise influenced the behaviour of representatives in the field.

Turning to the case now before it the Panel noted the implied allegation that the 'DEXA Placements DIY Guide' had been shared amongst the FROSST representatives and not just the Best Practice Team. As evidence the complainants had noted the statement 'Implementation of xxxx Market Expansion (e.g. DEXA placements) project placements ensuring an at least 40% diagnostic hit rate and at least 80% of all Osteoporotic patients identified are treated with Fosamax Once Weekly by December 2003' in a 2003 Performance Planning Form for FROSST sales representatives.

The complainants had also supplied two slides used to brief senior managers. One related to the DEXA placement programme and compared a number of features planned for 2002 and the outcome for the year to date (May 2002). The data stated that the planned number of osteoporotic patients was 33% of those scanned with the actual figure for the actual year to date being 30%. The planned number of 'Anecdotal Fosamax patients' was 80% whereas the year to date figure was 109%.

The second slide related to the objective for 2003 which was similar to 2002 ie 25-30 patients scanned per day with 30% being osteoporotic and 80% of those being treated with Fosamax Once Weekly.

The Panel noted Merck Sharp & Dohme's submission that the slides were used as briefing materials by managers to managers and were not within the scope of representative training materials and thus were not disclosed to the Authority but the content of the slides were part of briefings to representatives about their objectives.

The Panel considered that market expansion *per se* was not necessarily a breach of the Code. Any activity covered by the Code needed to comply with the Code. The Panel was concerned about the differences between the parties about the use of the 'DEXA Placements DIY Guide'.

The Panel did not consider that the Performance Planning Form provided evidence that, on the balance of probabilities, the 'DEXA Placements DIY Guide' had been used to train representatives. Neither the form nor the slides referring to market share linked the offer of the service to the promotion of Fosamax Once Weekly. Thus the Panel ruled no breach of the Code. These rulings were appealed by the complainant.

The Appeal Board noted that in Case AUTH/1859/6/06 the complainants had been anonymous and not contactable which was unfortunate as some of their current allegations could have been addressed if they had been involved in the previous case. The complaints procedure was designed to fully involve both parties. One of the unfortunate but unavoidable consequences of truly anonymous complaints was that the complainant forfeited their right as regard the appeal process.

The Appeal Board noted that the allegation now being considered was that Merck Sharp & Dohme had previously misled the Appeal Board. The Appeal Board considered that this was a serious allegation but that little evidence had been provided other than that previously considered. The Appeal Board did not accept that the documents supplied by the complainants that were not submitted in the previous case, demonstrated that, on the balance of probabilities, the Appeal Board had been misled. In the Appeal Board's view no credible evidence had been supplied.

The Appeal Board upheld the Panel's ruling that the Performance Planning Form provided no evidence that, on the balance of probabilities, the 'DEXA Placements DIY Guide' had been used to train representatives. Neither the form nor the slides referring to market share linked the offer of the service to the promotion of Fosamax Once Weekly. Thus the Appeal Board upheld the Panel's ruling of no breach of the Code.

In addition to their concerns about the provision of a service, the complainants also noted the following call rates cited in the Performance Planning Form: 'Ensure 100% coverage and frequency of 6 for 1:1 contacts on Super Targets (n=40) by December 2003; ensure 80% coverage and frequency of 4 for 1:1 contacts on Targets (n=80) by December 2003'.

The issue of excessive pressure on representatives to ignore the Code restriction of three unsolicited calls per year had been highlighted recently. Here was evidence that this was Merck Sharp & Dohme practice.

In the Panel's view representatives' briefing material should clearly distinguish between expected call rates and expected contact rates. The Panel noted that a 2003 presentation on the requirements of the Code, used with representatives, set out the requirements regarding call frequency. Nonetheless the Performance Planning Form was a stand alone document. The Panel noted that the form referred to contacts on targets and not call rates. The consequence of the form was that in addition to three 1:1 calls, representatives had to have three 1:1 contacts with targets as a result of meetings, requested call backs etc. An additional activity objective required representatives to 'Increase 1:1 GP activity (both call volume and call rate) relative to 2002 performance'. There was no mention that if 2002 performance was a call rate of 3 it was not possible to increase the call rate without breaching the Code.

The Panel considered that without further explanation that the 2002 call rate could not be increased beyond 3, the Performance Planning Form advocated a course of action which was likely to breach the Code. A breach of the Code was ruled. This ruling was not appealed. The Panel noted that a document detailing a 2006 salesforce incentive scheme clearly referred to the requirements of the Code regarding call frequency.

An anonymous group of employees of Merck Sharp & Dohme Limited complained about the provision of a service by the company and representatives' call rates.

1 Provision of a service

COMPLAINT

The complainants alleged that Merck Sharp & Dohme had misled the Authority in its appeal of the Panel's ruling of a breach of Clause 2 in relation to the conduct of the forearm DEXA placement initiative operated from 2002 to 2004 by the FROSST division of the Merck Sharp & Dohme sales force (Case AUTH/1859/6/06).

In Case AUTH/1859/6/06 the complainants had, *inter alia*, raised concerns regarding the ethical conduct of services offered by Merck Sharp & Dohme's musculoskeletal business unit, FROSST division. The complainants had considered the recently published case report for Case AUTH/1859/6/06, and now provided further documents for consideration by the Authority.

Merck Sharp & Dohme had claimed in its appeal that the 'DEXA placements DIY Guide' slide presentation was shared with a small group of representatives and not the entire FROSST sales division (the team with the first line sales responsibility for Fosamax promotion). This was untrue; the small group of representatives, comprised of six representatives and four sales managers, was the 'Fosamax Best Practice Team'. This team would meet two or three times each year to facilitate sharing of ideas (best practice) in relation to selling activities across the entire FROSST sales division. The FROSST division was comprised of approximately 60 representatives reporting to six regional managers who in turn reported to the national sales manager.

According to a considerable number of current and past members of the FROSST sales division the best practice team would 'cascade' ideas to each regional team. The slide presentation 'DEXA Placements DIY Guide' was one such example. FROSST division newsletters would illustrate this point; however, the complainants could not source examples of these on account of recent IT upgrades and subsequent file deletions. However, they provided a copy of the generic objectives document for FROSST sales representatives for 2003 – the 'Performance Planning Form'. In relation to Merck Sharp & Dohme's denial of an intended link between DEXA placements and product promotion the complainants noted the sub-heading under Objective 1:

- 'Implementation of xxxx Market Expansion (e.g. DEXA placements) project placements ensuring an at least 40% diagnostic hit rate and at least 80% of all Osteoporotic patients identified are treated with Fosamax Once Weekly by December 2003.'

Every member of the FROSST sales division based their personal objectives upon this generic template. However, as the complainants were not prepared to reveal their identity they could not provide named representatives' objective documents.

The complainants also provided copies of two slides on the national overview of the DEXA programme used by the national sales management team in presentations to Merck Sharp & Dohme's UK senior management. The slides were in relation to the 2002 programme throughput up to May and the plan for 2003. These slides correlated with the target of 80% Fosamax usage amongst patients identified as osteoporotic as stated within the representatives' objectives document. This supported the complainants' original contention in Case AUTH/1859/6/06 that the new managing director for Merck Sharp & Dohme UK, who was business unit director for the musculoskeletal business unit responsible for the FROSST sales division, was aware of the conduct and linkage of product promotion to service to medicine of this initiative. The FROSST national sales manager from 2002 to 2004 was appointed to co-chair Merck Sharp & Dohme's compliance oversight committee formed in response to Case AUTH/1814/3/06 and was therefore presumably consulted by the managing director to respond to the complainants' original complaint. The complainants noted the potential conflict of interest here given that the other co-chair of the compliance oversight committee was the business unit director responsible for the activities in question in Case AUTH/1814/3/6.

When writing to Merck Sharp & Dohme, the Authority asked it to respond in relation to Clauses 2, 9.1, 18.1 of the 2003 Code.

RESPONSE

Merck Sharp & Dohme was concerned that the Authority's procedures permitted the re-investigation of a complaint in this way, on the basis of further anonymous information from complainants who had chosen not to take part in or receive information on the earlier investigation. The company had serious reservations as to the propriety and fairness of such a course of action. Merck Sharp & Dohme was certain that there was no need for any current employee to seek anonymity if they wished to comment on or raise objections to any of its activities as the company maintained a confidential helpline for employees with any ethical concerns about its activities. Such concerns were taken seriously and investigated on their merits. Their reporting did not affect in any way the employee's standing within Merck Sharp & Dohme.

By seeking anonymity the complainants had excluded themselves from the full investigation of their concerns. They would not have seen Merck Sharp & Dohme's response to the previous complaint, its written submissions to the Appeal Board and did not attend the appeal itself. These would have provided proper opportunities to put forward further evidence and to challenge Merck Sharp & Dohme's evidence. To do so now, having read only the summary case report, amounted to an abuse of the Authority's processes. Further, this action caused Merck Sharp & Dohme to readdress issues fully subject to prior proceedings.

Merck Sharp & Dohme submitted that it did not mislead the Appeal Board in Case AUTH/1859/9/06 or in any of its prior responses. The allegation to the contrary was without foundation and appeared to be motivated more by an intention to damage Merck Sharp & Dohme's reputation than to identify new issues under the Code which merited the Authority's attention.

The complainants provided no evidence that the 'DEXA Placements DIY Guide' was sent to all representatives. Merck Sharp & Dohme further noted that the complainants did not refer to the DIY guide in their original complaint and had not been able to provide a copy of it or the names of anyone who had received it. There was nothing in the complainants' letter to suggest they had ever seen the contents of the DIY guide or had ever heard of it before they read the case report.

The DIY guide was disclosed voluntarily by Merck Sharp & Dohme, even though it was clearly not an officially sanctioned document; the company had

previously provided evidence suggesting that it had not been seen by anyone outside the small 'Best Practice Team'. Merck Sharp & Dohme found only one copy of the presentation during the course of its previous investigation and even the employee on whose computer the document was found could not recall the circumstances in which it was produced or who produced it. None of the other employees interviewed had any knowledge of the document.

At the appeal hearing Merck Sharp & Dohme suggested that whoever had sent or presented the document to the 'Best Practice Team' might have been told in no uncertain terms that its contents were unacceptable and should not be used in representative briefings. In any event, Merck Sharp & Dohme found no evidence that it was ever used in such briefings or sent to other representatives. Merck Sharp & Dohme presented positive evidence that the DIY guide had not influenced the behaviour of any of the representatives it interviewed, which tended to confirm its conclusion and their recollection that they had not seen it. Merck Sharp & Dohme had included it in its response to Case AUTH/1859/6/06 because more than one representative sat on the 'Best Practice Team' and so it strictly fell into the definition of material shown to representatives. Merck Sharp & Dohme made it quite clear in its response to the original complaint and in its appeal submissions that it should not be regarded as representative training materials either official or unofficial.

The Appeal Board must be regarded as having taken all the evidence into account in reaching its decision in Case AUTH/1859/6/06 and the complaint now at issue contained no further substantiated evidence in relation to the DIY guide which the Appeal Board could have considered. Merck Sharp & Dohme did not understand how the complainants' new and unsubstantiated allegation that the DIY guide was used in official Merck Sharp & Dohme briefing material for new representatives would have changed the Appeal Board's conclusion because such an allegation was effectively answered in Merck Sharp & Dohme's evidence and the evidence of its employees. As part of the appeal hearing, Merck Sharp & Dohme brought six witness statements given by former Fosamax representatives and their managers and offered those in evidence to the Chairman. While the Appeal Board did not require these statements as part of its decision, it was undeniable that these six statements, signed with a statement of truth and drawn up to the evidential standards of the civil and criminal courts of the UK, should be given greater weight than further anonymous and unsubstantiated allegations made by unknown persons not participating in proceedings.

The only 'new' evidence that the complainants had provided was an extract from a Performance Planning Form. This form referred to DEXA placements as an example of a market expansion activity. In Merck Sharp & Dohme's initial response to Case AUTH/1859/6/06 it explained that, because osteoporosis was best diagnosed by a DEXA scan, and Fosamax Once Weekly was indicated in patients with diagnosed osteoporosis, it was likely that some patients scanned as a result of a DEXA machine placement in general practice would be diagnosed as osteoporotic, and a proportion of these patients would likely be prescribed Fosamax Once Weekly. This was a market expansion activity in the same way that measuring blood pressure or blood sugar or peak flow was a market expansion activity. If undiagnosed or untreated disease was identified, the market for treatment of that disease expanded. This could not be a breach of the Code. What would be a breach of the Code would be to link the provision or sponsorship of a diagnostic service with the use of a particular product once a diagnosis had been made. Merck Sharp & Dohme was adamant that there was no such linkage in the case of Fosamax Once Weekly.

Merck Sharp & Dohme also noted that it had referred to market expansion or market development in the documents it disclosed to both the Panel and the Appeal Board; it was not new evidence. These references appeared in slide sets which represented representative briefings about performance goals for 2002 and 2003. The complainants did not refer to these documents but to slides used as briefing materials by managers to managers. These did not fall within the scope of representative training materials and were not, therefore, disclosed to the Authority. The information those slides contained supported rather than detracted from Merck Sharp & Dohme's original defence to the allegations. The objective of the DEXA programme was to increase the diagnosis and treatment of patients at high risk of osteoporosis. This was exactly as Merck Sharp & Dohme explained it in its original response to the Authority. There was no reference to the improper linkage of the DEXA service provision and the use of Fosamax Once Weekly.

Merck Sharp & Dohme reiterated that it was inevitable that a substantial proportion of patients diagnosed in the course of the DEXA programme would be treated with Fosamax Once Weekly. It was an important therapeutic choice for physicians to consider for patients with osteoporosis and it was not at all surprising, or improper, that many patients identified by scanning would be prescribed Fosamax Once Weekly. The reference to market share in the objectives form and the management slides simply reflected an estimate of the proportion of patients diagnosed to be at high risk of osteoporosis who might be prescribed Fosamax Once Weekly after a scan. The choice of Fosamax Once Weekly or another treatment was entirely one for the treating physician to make and was not linked to the provision of the scan. Merck Sharp & Dohme submitted that through its representatives it was perfectly entitled to engage in other activities to promote Fosamax Once Weekly. The concept that representatives might make promotional calls to discuss Fosamax Once Weekly with GPs, which were kept quite separate from any other involvement, such as it was, with the provision of a DEXA placement, was clearly referred to in Merck Sharp & Dohme's response, both to the Panel and to the Appeal Board.

The Authority asked for some information on market share for Fosamax Once Weekly. As mentioned above, the reference to 'market share' simply reflected an

estimate of the proportion of patients diagnosed to be at high risk of osteoporosis who might be prescribed Fosamax Once Weekly after a scan. Merck Sharp & Dohme could not see how determining whether market share went up, down, or stayed the same had any bearing on the complaint that it had misled the Appeal Board or that such evidence could substantiate any breach of the Code. Merck Sharp & Dohme promoted Fosamax Once Weekly in 2002 and 2003; if activity were successful in either maintaining or increasing market share, this could not constitute a breach of the Code. The DEXA placement programme was not a promotional activity.

In conclusion, therefore, Merck Sharp & Dohme denied any breach of the 2003 Code in relation to the DEXA programme and denied misleading the Appeal Board on in Case Auth/1859/6/06

PANEL RULING

The Panel noted that in Case AUTH/1859/6/06, although the 'DEXA Placements DIY Guide' had been considered by both the Panel and the Appeal Board, due to its submission by Merck Sharp & Dohme, this was the first complaint the Authority had received about the document. It was on this basis that this case, Case AUTH/1974/3/07, had proceeded.

The Panel noted that the osteoporosis audit took place in 2002 to 2004. Clauses 2 and 18.1 of the 2001 Code were the same as the 2003 Code. Clause 9.1 of the 2001 Code included the requirement of Clause 9.1 of the 2003 Code that high standards must be maintained at all times. Thus the Panel considered the matter in relation to the 2003 edition of the Code.

The Panel noted that the complainants had stated that the Best Practice Team (which according to Merck Sharp & Dohme, was a small number of representatives, managers and marketing specialists) to whom the 'DEXA Placements DIY Guide' was presented would share ideas in relation to selling activities across the entire FROSST sales division. At the appeal in Case AUTH/1859/6/06 the Appeal Board had been alarmed at the document and concerned that anyone could have produced it. The Appeal Board had ruled that there was no evidence on the balance of probabilities that the 'DEXA Placements DIY Guide' had been used to train representatives or had otherwise been disseminated beyond the meeting or to indicate that it had otherwise influenced the behaviour of representatives in the field.

Turning to the case now before it the Panel noted the implied allegation that the 'DEXA Placements DIY Guide' had been shared amongst the FROSST representatives and not just the Best Practice Team. As substantiating evidence for their allegation the complainants had noted the statement 'Implementation of xxxx Market Expansion (e.g. DEXA placements) project placements ensuring an at least 40% diagnostic hit rate and at least 80% of all Osteoporotic patients identified are treated with Fosamax Once Weekly by December 2003' in a 2003 Performance Planning Form for FROSST sales representatives.

The complainants had also supplied two slides used to brief senior managers. One related to the DEXA placement programme and compared a number of features planned for 2002 and the outcome for the year to date (May 2002). The data stated that the planned number of osteoporotic patients was 33% of those scanned with the actual figure for the actual year to date being 30%. The planned number of 'Anecdotal Fosamax patients' was 80% whereas the year to date figure was 109%.

The second slide related to the objective for 2003 which was similar to 2002 ie 25-30 patients scanned per day with 30% being osteoporotic and 80% of those being treated with Fosamax Once Weekly.

The Panel noted Merck Sharp & Dohme's submission that the slides were used as briefing materials by managers to managers and were not within the scope of representative training materials and thus were not disclosed to the Authority but the content of the slides were part of briefings to representatives about their objectives.

The Panel considered that market expansion *per se* was not necessarily a breach of the Code. Any activity covered by the Code needed to comply with the Code. The Panel was concerned about the differences between the company's submission about the use of the 'DEXA Placements DIY Guide' and the complainant's comments about its use.

The Panel did not consider that the Performance Planning Form provided evidence that, on the balance of probabilities, the 'DEXA Placements DIY Guide' had been used to train representatives. Neither the form nor the slides referring to market share linked the offer of the service to the promotion of Fosamax Once Weekly. Thus the Panel ruled no breach of Clause 18.1 and hence Clauses 9.1 and 2. In reaching this decision the Panel did not refer to the confidential market share data. These rulings were appealed by the complainant.

APPEAL BY COMPLAINANTS

The complainants alleged that an email from a national sales manager enclosing a slide set, 'DXA Placement Programme, Recording Data within Genesys' provided further unequivocal evidence of inappropriate ethical conduct of the DEXA initiative through recording the outcome of the placements, in terms of patients' diagnoses, on Merck Sharp & Dohme's electronic territory management system (ETMS). The programme breached Clause 18 of the Code as the complainants had been informed from a significant number of sales representatives employed in the FROSST division at the time that they were instructed to ensure that 80% of patients identified as being osteoporotic were prescribed Fosamax on account of this target being incorporated into their annual objectives documents as previously provided.

The complainants noted the email sent from a

national sales manager for the FROSST GP sales division at the time, to the regional sales managers and copied to the then Fosamax marketing manager and the Fosamax business analyst. This email requested that regional sales managers instruct their sales representatives to enter data regarding the DEXA placement program into the company's ETMS. Whilst the complainants had copies of this email that had been forwarded to representatives, to provide the Authority with these copies would potentially expose their colleagues which was not acceptable in light of the potential impact on the individuals concerned. The wording of the email in question provided sufficient evidence to the Appeal Board that the presentation attached to the email was intended for implementation by, and disseminated to, all FROSST division sales representatives.

The slide presentation attached to the email told representatives how to enter data about the surgery DEXA placements into the ETMS system. The complainants alleged that such activities were completely inappropriate conduct for pharmaceutical sales representatives; why were representatives being provided with this audit data? Indeed, this activity in its own right potentially constituted a breach of Clause 18.1 of the 2003 Code. The supplementary information of Clause 18.1 Provision of Medical and Educational Goods and Services stated: '(v) Neither the company nor its medical/generic representatives may be given access to data/records that could identify, or could be linked to, particular patients'.

The complainants submitted that the majority of the DEXA placements in question involved a radiographer scanning 20-30 patients on one day at a particular surgery. Of these, routinely 6-10 patients would be identified as osteoporotic and requiring treatment. Whilst they did not have evidence for, and were not suggesting that sales representatives had access to individual patient records which would clearly be a breach of patient confidentiality, reporting of the diagnostic data to the sales representatives without the patient's prior consent could well represent a breach of the Code. One might never know whether the patients in question would be happy to have, albeit, anonymised data regarding their medical history entered onto a pharmaceutical company's data base.

Reporting of the diagnostic outcomes of the DEXA placements would presumably require the representatives to request this information directly from the surgery staff or from the radiographers themselves. The complainants noted that the DEXA placements were referred to as 'Fos Market Expansion Programmes' (presumably 'Fos' referring to Fosamax) rather than 'Osteoporosis Market Expansion Programmes'. This provided further evidence to support the previous allegations that senior management intended that the representatives responsible for implementing these programs would conceptually and practically link provision of the DEXA service to resultant sales of Fosamax.

The complainants alleged that the email referred to the fact that entry of data into the ETMS would permit analysis at both HQ and regional sales team levels. Not surprisingly, the analysis in question correlated Fosamax sales performance against DEXA activity in particular postal bricks.

The complainants noted that Merck Sharp & Dohme stated that the only 'new' evidence they had submitted above and beyond that previously reviewed in Case AUTH/1859/6/06 was an extract from a generic Performance Planning Form. The complainants clearly understood that Clause 18 of the Code permitted representatives to introduce a service to medicine to health professionals and they had not raised any objection to the concept of expanding the market in terms of the numbers of patients identified, diagnosed and treated. The complainants also accepted Merck Sharp & Dohme's point that a significant percentage of patients diagnosed with osteoporosis by the DEXA placement initiative would be treated with Fosamax as a consequence of the prevailing market dynamics. The issue with the conduct of this programme was the pressure placed upon sales representatives to ensure that 80% patients identified by DEXA placements, that they themselves had set-up, received Fosamax. The explicit link between market expansion programs and resultant product usage was stated in the Performance Planning Form:

> 'Implementation of xxxx Market Expansion (e.g. DEXA placements) projects ensuring an at least 40% diagnostic hit rate and at least 80% of all Osteoporotic patients identified are treated with Fosamax Once Weekly by December 2003.'

Representatives were required to select which practices would be offered the service, to act as a point of contact for the surgery with the radiographer and then to ensure that 80% of osteoporotic patients be treated with Fosamax. Clearly, a sales representative's primary responsibility was to sell product and thus all of their activities in the process of setting up a DEXA placement would be geared towards this objective. Obviously, this would influence which surgeries were chosen for provision of the service and inevitably encourage representatives to sell Fosamax to the GPs to whom they had provided a valuable diagnostic service. Armed with the diagnostic data from each placement, the national sales management team was able to apply an 80% target treatment rate for those patients identified as osteoporotic and correlate service to medicine placement against increased sales return in particular postal bricks, as intimated in the national sales manager's email. The email also stated that entry of the diagnoses data for the DEXA placements would enable the regional sales managers to analyse the impact of these programs – self-evidently, a regional sales manager was concerned with, and conducted analyses upon, sales performance; the analysis in question related to Fosamax sales performance associated with the DEXA placements.

The complainants noted that the reason they requested anonymity was self-evident from Merck Sharp & Dohme's conduct in responding to the complaint. Merck Sharp & Dohme blatantly refused to accept that it had breached the Code in this matter, regardless of

the fact that several staff members raised concerns about the conduct of this program at the time. The complainants drew parallels with this case and Case AUTH/1814/3/06 in that regard.

The complainants alleged that Merck Sharp & Dohme's counter submission that they were motivated by an intention to damage Merck Sharp & Dohme's reputation was remarkable. The unethical actions led by Merck Sharp & Dohme senior management that resulted in the company's suspension from the ABPI during 2006 irreversibly damaged collective and individual reputations, at least for the foreseeable future. The intention of raising concerns regarding ethical conduct across Merck Sharp & Dohme's business with the Panel was to purge a company that the complainants were once proud to serve, of unethical practice once and for all. Upon reading the case report for Case AUTH/1859/6/06 the complainants were very disappointed to realise that the new open and honest ethical culture presented during the last 12 months at Merck Sharp & Dohme in response to Case AUTH/1814/3/06, was not prepared to expose all of the skeletons in the corporate closet. The new senior management team had an opportunity to reveal to the Panel that the compliance culture at Merck Sharp & Dohme had been institutionally flawed until Case AUTH/1814/3/06. This senior management team had not grasped that opportunity and rather mis-represented historical conduct in relation to its original defence of Case AUTH/1859/6/06. Worse still, when the Panel correctly ruled a breach of Clause 18.1 and 2, Merck Sharp & Dohme senior management misled the Appeal Board.

The complainants noted that without revealing their identities or the identities of colleagues that had provided information regarding the conduct of the DEXA placement initiative they were unable to provide documentary evidence to counter Merck Sharp & Dohme's claims regarding the limited dissemination of the 'DEXA Placements DIY Guide'. Indeed, a recent company-wide records management initiative to clean-up and delete 'non-essential' historical files/emails/etc meant that most records of the company's programs at this time were lost. The complainants nonetheless submitted that they were sincerely and honestly convinced that all representatives in the FROSST division during 2002 to 2004 were instructed to ensure that the DEXA placement programme directly contributed to growth of their territories' Fosamax sales. This was supported by the additional evidence submitted regarding reporting of diagnostic outcomes of the DEXA placements on Merck Sharp & Dohme's ETMS.

COMMENTS FROM MERCK SHARP & DOHME

Merck Sharp & Dohme stated that it was remarkable, given that the essence of the complaint was that it had misled the Appeal Board in Case AUTH/1859/6/06, that the appellants sought to rely on two documents, both of which had already been disclosed voluntarily by Merck Sharp & Dohme and were before the Appeal Board when it considered Merck Sharp & Dohme's appeal in Case AUTH/1859/6/06. Had the complainants taken part in the earlier appeal, as they were entitled to do and had done on this occasion, they would have been able to make submissions on both these documents, at the proper time, before and during the appeal in Case AUTH/1859/6/06. The Appeal Board's ability to make a fair and final ruling must be compromised if complainants were allowed to manipulate the Authority's procedures in this way. It was also the case that the complainants on this occasion, relied on a document (already disclosed by Merck Sharp & Dohme itself in any event) a copy of which they submitted to the Authority after the date by which Merck Sharp & Dohme's response to the complaint had been received by the Authority. Merck Sharp & Dohme had had no opportunity to make submissions on this aspect of the appeal until this letter.

Merck Sharp & Dohme submitted that the complainants had relied on a PowerPoint presentation telling representatives how to enter certain data relating to the DEXA programme into the company's ETMS. This was simply another copy of a document that Merck Sharp & Dohme submitted to the Appeal Board for its appeal against the Panel's ruling in Case AUTH/1859/6/06. The copy that Merck Sharp & Dohme submitted was provided by one of the recipients named on the covering email from a national sales manager. The complainants seemed unaware that the Appeal Board had already seen this document and read and heard submission on it from Merck Sharp & Dohme.

Merck Sharp & Dohme had referred to the document at the appeal to show that no instructions were given to enter sales metrics onto the ETMS as alleged in Case AUTH/1859/6/06. Merck Sharp & Dohme noted that there was simply no field in the ETMS in which sales metrics could have been entered. It was true that the ETMS recorded how many DEXA placements had been made and their location. Merck Sharp & Dohme could speculate, knowing the average rate of scanning and the incidence of osteoporosis and osteopenia generally to be found in the at-risk population, as to how the market for osteoporosis treatments, including Fosamax, could expand. This did not, however, involve the disclosure by either practice staff or prescribers of any confidential data. The sales representatives would simply have to know whether the radiographers operating the DEXA machines actually attended the practice as arranged; the rest of the data could simply be derived as 'best guesses' from known metrics, such as the usual rate of scanning. In some cases the radiographers might have told representatives how many scans had been performed. This was a sensible means of keeping the service provision under review. It would clearly not be sensible for Merck Sharp & Dohme to invest in the service if very few patients were benefiting from it or if organisational problems could be identified which were preventing at-risk patients from taking advantage of it. Such considerations could not be described as relating to product promotion nor did they amount to a breach of Clause 18.1 of the 2003 Code. There was and never

had been any suggestion of inducements being offered to any prescriber or member of the health professions in connection with the DEXA service.

Merck Sharp & Dohme noted that in its appeal in Case AUTH/1859/6/06, it brought to the hearing signed witness statements from a range of representatives from the FROSST team that described to the best of their recollection what involvement they had had with the service. In no case, had this included entering sales metrics on the ETMS. The complainants, on the other hand, merely offered not only unattributed and untestable hearsay but also pure conjecture.

Merck Sharp & Dohme noted that the second element of the complainants' appeal returned yet again to the set of slides described as the 'DEXA placements DIY Guide', which Merck Sharp & Dohme disclosed with its response to Case AUTH/1859/6/06. These slides were not authorized by Merck Sharp & Dohme and did not represent any official training provided to representatives. The Appeal Board accepted Merck Sharp & Dohme's submission that there was no evidence that these slides had ever been used to train representatives generally and might not have been seen by anyone beyond a small group of perhaps ten managers and representatives. In the appeal in Case AUTH/1974/3/07 the complainants had nothing new to say about these slides; they merely recorded their 'conviction' that their assumptions were true. These assumptions appeared to be based not on their own experiences or observations but allegedly on those of unnamed colleagues who were not party to the complaint. Merck Sharp & Dohme had already noted in its response that the complainants did not refer to these slides until after they had seen them referred to in the case report for Case AUTH/1859/6/06. This strongly suggested that they had no knowledge at all of their existence before then. This in itself tended to support Merck Sharp & Dohme's submissions that there was no evidence that the slides were disseminated to representatives generally.

FURTHER COMMENTS FROM THE COMPLAINANTS

The complainants noted Merck Sharp & Dohme's view that they were attempting to manipulate the Authority's procedures. The complainants assured the Authority that this was absolutely not so and that Case AUTH/1974/3/07 stemmed from their collective outrage at the substance of Merck Sharp & Dohme's appeal in Case AUTH/1859/6/06 which only became apparent to them on publication of the case report.

The complainants noted that Merck Sharp & Dohme had stated that data entry on the ETMS relating to diagnostic outcomes of patients that attended the DEXA placements was based upon 'best guesses'. This was not so. Representatives were asked to ascertain this data from either the practice staff or the radiographer for every DEXA placement that took place. The complainants noted that in the slide presentation relating to data entry regarding the DEXA placements, representatives were not advised to 'best guess' this information. If the fields were created in the ETMS system with the intention of being filled by best guesses, why did they exist in the first place? On this basis, all that would be required to estimate the number of patients in each diagnostic category, and therefore estimate how many patients were treated with Fosamax, could be derived from the total number of patients scanned on the day(s).

The complainants alleged that Merck Sharp & Dohme also failed to comment upon why the ETMS marker relating to the DEXA placement was referred to as 'Fos Market Expansion Programmes' rather than 'Osteo(porosis) Market Expansion Programmes'. The complainants noted their previous comments regarding patient consent. Patients' diagnostic data was proactively requested by Merck Sharp & Dohme senior management for entry into the ETMS by representatives as demonstrated in the presentation attached to the email to the FROSST regional sales management group. Why would the osteoporosis/ osteopenia data fields have been created if they were to be populated with guess work? A knowledge of the number of osteoporotic diagnoses would allow for application of the 80% Fosamax treatment target set for representatives in their annual Performance Planning Grid objectives document that was provided to the Panel.

The complainants sincerely hoped that the Appeal Board would re-instate the original rulings in relation to Case AUTH/1859/6/06 as the Panel had arrived at the right verdict first time around.

APPEAL BOARD RULING

The Appeal Board noted that in Case AUTH/1859/6/06 the complainants had been anonymous and not contactable. This was unfortunate as some of the complainants' current allegations could have been addressed if they had been involved in the appeal in Case AUTH/1859/6/06. The complaints procedure was designed to fully involve both parties. One of the unfortunate but unavoidable consequences of truly anonymous complaints was that the complainant forfeited his right as regards the appeal process.

The complainants had read the published outcome in Case AUTH/1859/6/06 and had shortly thereafter submitted the current complaint which included allegations about the DEXA Placement DIY Guide and two new documents, the Performance Planning Form and two slides on the national overview of the DEXA programme. As the complaint satisfied the criteria set out in Paragraph 5.1 of the Constitution and Procedure it was allowed to proceed.

The Appeal Board was concerned that the complainants had not taken part in the appeal in Case AUTH/1859/6/06 but instead had submitted a fresh complaint.

The Appeal Board noted the complainant's request that the Appeal Board ruling in Case AUTH/1859/6/06 be

overturned. This was not possible, that case had completed.

The Appeal Board noted that the allegation now being considered was that Merck Sharp & Dohme had misled the Appeal Board in the previous case. The Appeal Board considered that this was a serious allegation but that little evidence had been provided other than that previously considered by the Appeal Board as part of the appeal in Case AUTH/1859/6/06.

The Appeal Board noted Merck Sharp & Dohme accepted that the reference to 'FOS Market Expansion Programme' was unfortunate. Further the company stated that whilst it was prepared to accept that the Performance Planning Form might have been used, it had no evidence either way as to whether it was an authentic document. Merck Sharp & Dohme had not found the document when responding to Case AUTH/1859/6/06. Merck Sharp & Dohme stated that it would have expected to have found it.

The Appeal Board did not accept that the documents supplied by the complainants, that were not submitted in the previous case, demonstrated that, on the balance of probabilities, the Appeal Board had been misled. In the Appeal Board's view no credible evidence had been supplied.

The Appeal Board upheld the Panel's ruling that the Performance Planning Form provided no evidence that, on the balance of probabilities, the 'DEXA Placements DIY Guide' had been used to train representatives. Neither the form nor the slides referring to market share linked the offer of the service to the promotion of Fosamax Once Weekly. Thus the Appeal Board upheld the Panel's ruling of no breach of Clause 18.1 and hence no breach of Clauses 9.1 and 2.

Following its consideration of this case the Appeal Board was concerned about the difficulties of dealing with anonymous complaints particularly when a complainant who had been non contactable made a subsequent complaint. The Appeal Board was also concerned that this might lead to an abuse of process.

2 Representative call rates

COMPLAINT

The complainants noted the following call rates cited in the Performance Planning Form:

3 'Ensure 100% coverage and frequency of 6 for 1:1 contacts on Super Targets (n=40) by December 2003

4 Ensure 80% coverage and frequency of 4 for 1:1 contacts on Targets (n=80) by December 2003.'

The issue of excessive pressure imposed by companies on representatives to ignore the Code restriction of three unsolicited calls per year had recently been highlighted in the industry press. Here was clear evidence that this practice had been imposed by senior management at Merck Sharp & Dohme for many years.

When writing to Merck Sharp & Dohme, the Authority asked it to respond in relation to Clauses 15.2, 15.4 and 15.9.

RESPONSE

Merck Sharp & Dohme noted that the complainants' final, and only new, allegation related to call rates on the Fosamax target audience in 2003, as referred to in an unidentified representative's Performance Planning Form. The Performance Planning Form related to call rates generally, rather than only or specifically to unsolicited call rates. The complainants had not provided any evidence that FROSST representatives were pressured to breach Clause 15.4 in respect of unsolicited call rates. There was no breach of the Code if representatives made promotional calls or contacts with doctors at their request and there was no breach of the Code if they were rewarded for doing so. The call rates assessed in the representative's objectives analysis could include contacts of both types. Merck Sharp & Dohme provided a copy of a presentation made to trainee representatives at their foundation training in 2003 which explained the requirements of the Code in relation to call rates. Merck Sharp & Dohme also enclosed relevant extracts from the 2003 Sales Incentive Plan for the relevant representatives; for the purposes of bonus calculation, the total volume of contact activity of all types was measured against an industry average. For completeness, Merck Sharp & Dohme provided a copy of its 2006 Sales Incentive Plan, which now included a prominent reference to Clause 15.4.

In conclusion, Merck Sharp & Dohme denied any breach of the Code.

PANEL RULING

The Panel noted that the complainants had referred to two activity objectives cited on the Performance Planning Form. Firstly 'Ensure 100% coverage and frequency of 6 for 1:1 contacts on Super Targets (n=40) by December 2003' and 'Ensure 80% coverage and frequency of 4 for 1:1 contacts on Targets (n=80) by December 2003'.

The Panel noted that the supplementary information to Clause 15.4 of the 2003 Code stated that the number of calls made on a doctor each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or a visit to follow up a report of an adverse reaction. Thus although a representative might proactively call on a doctor or other prescriber three times a year, the number of contacts with that health professional in a year might be more than that. In the Panel's view material should clearly distinguish between expected call rates and expected contact rates.

The Panel noted that a 2003 presentation on the requirements of the Code, used with representatives,

set out the requirements of Clause 15. Nonetheless the Performance Planning Form was a stand alone document. The Panel noted that the form referred to contacts on targets and not call rates. The consequence of the form was that in addition to three 1:1 calls, representatives had to have three 1:1 contacts with targets as a result of meetings, requested call backs etc. As an additional activity objective the Performance Planning Form also required representatives to 'Increase 1:1 GP activity (both call volume and call rate) relative to 2002 performance'. There was no mention that if 2002 performance was a call rate of 3 it was not possible to increase the call rate without breaching the Code.

The Panel considered that without further explanation that the 2002 call rate could not be increased beyond 3, the Performance Planning Form advocated a course of action which was likely to breach the Code. A breach of Clause 15.9 was ruled. This ruling was not appealed. The Panel noted that a document detailing a 2006 salesforce incentive scheme clearly referred to the requirements of Clause 15.4 regarding call frequency.

Complaint received	**1 March 2007**
Case completed	**14 June 2007**