ANONYMOUS EMPLOYEES v MERCK SHARP & DOHME

Medical and educational goods and services

An anonymous complainant raised concerns on behalf of a number of Merck Sharp & Dohme's employees about services offered by the company.

For approximately two years (2002 to 2004) a sales division was responsible for implementing and managing a service which involved placement of bone scanners (DEXA scanners) in general practices to improve the diagnosis of patients with osteoporosis. Sales metrics were considered when deciding which practices should be offered the scanners. Representatives were required to input into the company's electronic territory management system the number of patients that went on to Fosamax (alendronate) as a result of their scan. The conduct of this programme appeared to be in breach of the 2003 Code in the same fashion as the programme at issue in a previous case involving Merck Sharp & Dohme, Case AUTH/1814/3/06.

The Panel noted that a funding proposal included a section on the prescribing environment. The group being considered for receiving a DEXA scanner was said to be currently in the process of updating prescribing guidelines which would include alendronate. Details of the alendronate market share were provided in the proposal.

The Panel noted that a slide set 'DEXA Placements DIY Guide', provided by Merck Sharp & Dohme, was not approved by the company. According to Merck Sharp & Dohme it had been used with a small group of representatives.

One of the slides was headed 'Identify Surgery' listing the criteria as 'sales data, Fosamax target, speaker meeting, influential contact'. For some reason representatives were advised on the day that scanning took place to 'beware of staff'. Inclusion details listed, *inter alia*, 'Rx update FOW/DPMO' and 'sales background'. The sales review criteria were listed as 'market potential, market share FOW vs DPMO, market trend, size market and sales per GP'. Support information included 'GP RX intent'. No official Merck Sharp & Dohme training slides had been submitted.

The checklist for the service, which had also not been authorized by the company, included a list of triggers such as 'GPs are reluctant to start therapy for patients they believe have osteoporosis without a [bone] scan' and 'Fosamax is bisphosphonate of choice'. The outcomes/monitoring included what treatment was initiated if any.

The Panel considered that on the information before it there was no evidence that the representatives had been briefed about the need to separate the provision of medical and educational goods and services from the promotion of medicines. The service would be seen by representatives as being linked to the promotion of Fosamax. This would be reinforced to those representatives shown the slides and given the check list. This was totally unacceptable.

The supplementary information to the 2003 Code stated that materials relating to the provision of medical and educational goods and services must be examined by the Code of Practice signatories and this had not happened with regard to some of the materials. The template letters for patients did not state that the service was sponsored by Merck Sharp & Dohme. The slides linked the provision of the service to the use of Fosamax. The Panel considered that the arrangements were unacceptable. High standards had not been maintained and the circumstances brought discredit upon the pharmaceutical industry; breaches of the Code including Clause 2 were ruled.

The Panel decided to report Merck Sharp & Dohme to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

Upon appeal the Appeal Board noted Merck Sharp & Dohme's submission that the purpose of the programme was to expand the diagnosed population of osteoporotic patients. The programme had started to wind down in the latter half of 2003 from whence no new representatives were trained; only those already trained and experienced on the programme continued to work on it. Managers had continued to provide some training by mentoring in the field. This was one of the reasons for the lack of documentation. Nonetheless, the Appeal Board considered that the company should have been able to produce job bags for the relevant training material which governed the representatives' activities from the latter part of 2003 onwards.

The Appeal Board noted that the company was able to provide little evidence about the provenance, status and use of the slide set 'Placements DIY Guide' and the checklists. The Appeal Board was alarmed at the slide set and concerned that anyone could have produced it. The company's investigation indicated that the slides had been discussed at a best practice meeting typically attended by one representative from each of the six sales regions and four regional managers. The basis of the discussion and its outcome were not known. The Appeal Board considered that there was no evidence on the balance of probabilities that the material 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.

The Appeal Board further noted another document 'Guide to Proposal Development' which related to funding for osteoporosis selective case finding in primary care. Under a heading of 'Benefits of the project' was stated 'Environment positive for Fosamax with high market share in locality and inclusion in clinical guidelines'. The Appeal Board was concerned at this statement but noted that to the best of Merck Sharp & Dohme's knowledge, no

proposals had ever taken place, nor was there any evidence that the document had influenced representatives' behaviour.

The Appeal Board understood why the Panel was concerned about the material. However, it considered that the complainant had not established on the balance of probabilities that the arrangements amounted to a breach of the Code.

With regard to the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure the Appeal Board noted its comments above and its rulings of no breach of the Code. The Appeal Board decided to take no further action.

The complainant alleged that the Special Products Business Unit appeared to engage in 'return on investment' (ROI) calculations in respect of any grants provided to specialist hospital units intended to improve patient care in the relevant therapeutic areas. Such calculations appeared to be at odds with the provision of unconditional grants.

The Panel noted that the complainant acknowledged that he did not have evidence of malpractice. Merck Sharp & Dohme could only identify two unconditional grants as it rarely gave such grants. The business unit manager did not make ROI calculations in relation to grants unrestricted or otherwise. Merck Sharp & Dohme provided evidence relating to two grants to hospitals; one, an educational grant of £10,000 and the other for £1,000 for developments in a cardiac care unit. There was no evidence that ROI calculations had been made. The Panel considered that there was no evidence that Merck Sharp & Dohme had included ROI calculations in relation to grants. Thus no breaches of the Code were ruled.

The complainant alleged that discussion with former members of the Maxalt team would bring into question the probity of conduct in respect of so-called 'switch/upgrade' programmes that were intended to support a change in prescribing at a practice level from GlaxoSmithKline's medicine, Imigran, to Maxalt. Given Maxalt's cost advantages it was not clear whether this practice was at odds with the Code.

The Panel noted that the material supplied by Merck Sharp & Dohme set out the arrangements for a number of migraine therapy review services offered in 2001, 2003 and 2004 onwards. If a practice decided to proceed with such a review a pre-agreed service specification would be signed which was flexible to suit the needs and prescribing habits of the practice. The practice could specify which patients should be included/excluded and set its own preferred treatment algorithm. The doctor was responsible for deciding whether to implement any change in therapy.

It appeared that all of the materials had been seen by the company. The materials did not feature the Maxalt product logo and rarely even used the product name. The Panel noted that a bar chart depicting the percentage of patients with 2 hour headache response featured the Maxalt product name but the Panel did not consider that such use was sufficient to render the material in breach of the Code. There was no representatives' briefing material *per se* provided. On the basis of the material before it there was no evidence that the migraine therapy review was intended to support a switch from Imigran to Maxalt as alleged. No breaches of the Code were ruled.

An anonymous complainant complained on behalf of an undisclosed number of Merck Sharp & Dohme's employees about services offered by Merck Sharp & Dohme Limited.

COMPLAINT

The complainant alleged that in light of recent internal communications regarding the Code breaches relating to Merck Sharp & Dohme's hypertension and diabetes audit programmes supported by the Cozaar product team (Case AUTH/1814/3/06), an unofficial self-appointed group of committed Merck Sharp & Dohme employees, from all sectors of the UK business and with substantial collective experience in sales, had populated the following 'Consensus Statement' of concerns regarding Code adherence by Merck Sharp & Dohme in the UK.

Consensus Statement

Whilst the complainant firmly believed that Merck Sharp & Dohme had contributed significantly to improving the health of the nation through the introduction of numerous innovative medicines during the last three decades and support of several excellent examples of ethical patient care programmes in collaboration with the NHS, the following merited cause for concern in light of the recent Clause 2 breach (Case AUTH/1814/3/06) relating to the hypertension/diabetes nurse advisor programmes:

1 Musculoskeletal Business Unit, FROSST Division: For approximately two years between 2002 and 2004 the FROSST GP Sales Division led by the national sales manager was responsible for implementing a programme which involved one day placement of forearm bone scanners (DEXA scanners) in general practices keen to improve the diagnosis of patients with osteoporosis. Representatives employed within the FROSST division at the time had informed the group that they were required to manage this programme from start to end. Furthermore, sales metrics were considered when decisions were made regarding which practices should be offered the scanners. The group's primary concern related to its finding that representatives were required to input into the company's electronic territory management system (ETMS) the number of patients that went on to Merck's medicine Fosamax (alendronate) as a result of their scan. Accordingly, the conduct of this programme appeared to be in breach of Clause 18.1 of the 2003 Code in exactly the same fashion as the hypertension/diabetes programme in Case AUTH/1814/3/06.

A particular concern in relation to the programme was that the newly appointed Managing Director for Merck Sharp & Dohme in the UK was the FROSST national sales manager's line manager at the time and therefore was presumably completely aware and

agreeable to the manner in which this programme was implemented.

2 Special Products Business Unit: Although the group had not acquired specific evidence of malpractice, the Special Products Business Unit appeared to engage in 'return on investment' (ROI) calculations in respect of any grants provided to specialist hospital units intended to improve patient care in the relevant therapeutic areas. Such ROI calculations appeared to be at odds with the provision of unconditional grants.

3 Migraine Team: Merck Sharp & Dohme had employed a small team devoted to the promotion of its migraine medicine Maxalt for a number of years. Discussion with former members of this team would bring into question the probity of conduct in respect of so-called 'switch/upgrade' programmes that were intended to support a change in prescribing at a practice level from GlaxoSmithKline's medicine, Imigran, to Maxalt. Given the cost advantages provided by Maxalt, the group was not absolutely clear whether this practice was at odds with the Code.

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

RESPONSE

Merck Sharp & Dohme noted that the allegations were unsupported by documents, and were unlimited in time and were, in certain respects, a little difficult to characterise as breaches of the Code. Merck Sharp & Dohme had, however, endeavoured to read the allegations as potential breaches of Clauses 2, 9.1 and 18.1 of the 1998, 2001 and 2003 Codes, since the activities to which the allegations related all took place before January 2006.

Musculoskeletal Business Unit, FROSST Division

Merck Sharp & Dohme submitted that between 2000 and 2004, it had supported a programme whereby general practitioners were offered the services of a radiographer to perform bone density scans on patients identified as being at risk from osteoporosis. The services were provided by a third party and involved the radiographer attending the surgery for one day, during which bone density scans were performed on typically around 25 patients and the results provided to their GP. The patients were identified by the practices themselves and invited to the scanning session by a letter from their own GP. In some cases, the DEXA scanners were purchased by Merck Sharp & Dohme and lent to the third party specialist provider. As a result of the scan, some patients would have been prescribed treatment for osteoporosis.

Merck Sharp & Dohme submitted that its interest in the therapeutic sector prompted its provision of a service. This was the case for most companies. Importantly, however, the prescription of Fosamax Once Weekly was not a condition of the provision of the service and, as far as Merck Sharp & Dohme was aware, at no time was such a representation made to any GP. Fosamax Once Weekly was one of the brand leaders in osteoporosis treatment between 2002 and 2004 and it was likely, therefore, to have been prescribed for a proportion of patients scanned in the DEXA programme. Such prescription would only have taken place after assessment of the patient's suitability for treatment by their GP and a decision by the GP to prescribe Fosamax Once Weekly rather than other available treatments for osteoporosis.

Merck Sharp & Dohme regarded the service as one which both enhanced patient care and benefited the NHS since the availability of bone density scanning to NHS patients was limited, such that a substantial proportion of at risk patients did not have access to bone density scanning at all. The objectives were described in a Merck Sharp & Dohme briefing document drafted in 2001 as to 'Facilitate the earlier diagnosis and active management of osteoporosis in the Primary Care environment' and 'Facilitate the process of implementation of the Royal College of Physicians Bone and Tooth Society guidelines placing greater responsibility with the General Practitioner for the diagnosis and management of the disease'. The service was of particular benefit to patients in rural areas who were able to attend their own surgery for a diagnostic test that might otherwise be available only at a district hospital. It was likely that the majority of at risk patients who were offered scanning were over 60 and would have had risk factors such as previous low trauma facture.

Merck Sharp & Dohme submitted that its representatives told GPs about the DEXA scanning service. Typically, this arose in response to observations made by the GP about the lack of provision of such scanning by their local NHS provider. Although a bone density scan was not a prerequisite to treatment for osteoporosis in at risk patients, it was regarded as best practice and Merck Sharp & Dohme would not encourage physicians to prescribe any osteoporosis treatment without the results of such a scan.

Merck Sharp & Dohme submitted that if the GP wished to take up the offer of the service, the representative would notify his or her manager and contact the third party specialist provider. Thereafter, the third party specialist provider contacted the practice and arranged for the scanning day to take place. The representatives were not involved in the selection of patients. In some cases GPs used template letters provided by the representatives to invite patients to the scanning day and to inform them of their results. In some cases, Merck Sharp & Dohme provided a grant to the practice to help pay for overtime worked by practice nurses in identifying at risk patients.

Merck Sharp & Dohme submitted that it was likely that the representative contacted the practice on the day that the scans were to take place or shortly thereafter to check that the administrative arrangements had gone smoothly. Representatives did not know how many patients were prescribed Fosamax Once Weekly as a result of the scan nor did they have access to any individual patient data. They would, however, be able to infer the approximate number of prescriptions simply from their knowledge of the number of scanning days which had taken

place, the average number of patients scanned who were likely to be diagnosed with osteoporosis and the geographical market share of Fosamax Once Weekly. It was this information which was reported back to their mangers and might, in some cases, have been entered onto the ETMS. However, Merck Sharp & Dohme had examined the information currently held in the ETMS and there seemed to be no available field in which Fosamax Once Weekly sales data linked to the DEXA programme could have been entered. None of the employees interviewed recalled that such data were entered onto the ETMS. The programme finished in 2004.

Merck Sharp & Dohme submitted that it had interviewed the two representatives involved in the programme from 2000 who remained in Merck Sharp & Dohme's employment and had found no evidence to support the allegations. Specifically, while representatives managed some of the administrative arrangements for the programme, the medical and technical aspects were left entirely to the radiographer, the GP and the practice staff. Merck Sharp & Dohme did not consider this to be a breach of Clause 18.1 of the 1998, 2001 or 2003 Codes. The provision of the service was done in such a way as not to be an inducement to prescribe any medicine.

Merck Sharp & Dohme submitted that it had not found any evidence that sales metrics were considered when decisions were made regarding which practices were offered the scanners. None of those interviewed recalled any case of a practice requesting the service being turned down. Indeed, a Merck Sharp & Dohme briefing document describing the funding of osteoporosis projects prepared in 2002 noted that 'No sales data, Return on Investment (ROI) or script impact calculations should be included with the proposal' (provided). Consistent with this, Merck Sharp & Dohme included an example of a completed proposal form in which five benefits of the project were described. The benefits to Merck Sharp & Dohme were described as 'environment positive for Fosamax with high market share in locality and inclusion in clinical guidelines' and 'opportunity for Merck Sharp & Dohme representatives to promote the service to practices thereby offering an added value service'. Clearly, it was likely that practices who requested the service were ones who would consider prescribing Fosamax, since they would have heard about the scanner during a visit from the Fosamax representative. Merck Sharp & Dohme confirmed that it was not its policy only to offer the scanning service to high prescribing practices, although it might be anticipated that it would be expected that such practices would take up the offer in larger numbers than low or non-Fosamax prescribing practices.

Merck Sharp & Dohme provided materials relating to the DEXA programme, given to representatives, nurses, doctors and patients, found in its archives. Merck Sharp & Dohme had not identified formal training materials on the DEXA programme but included in the documents were a number of slide sets of presentations made by managers to representatives. In a few of these documents there was a suggestion that the DEXA programme would lead to increased sales of Fosamax Once Weekly.

Whilst it must be regarded as an inevitability that sales of the market leading product would increase if the use of a diagnostic test which was a prerequisite to its prescription were to increase, there was no suggestion in this documentation that prescribing of Fosamax was a requirement or consideration in the placement of DEXA machines. That said, Merck Sharp & Dohme recognised that it did not represent best practice to reinforce such a suggestion in the minds of representatives. Merck Sharp & Dohme's revised Standard Operating Procedures (SOPs) and training schedule would take account of this.

Merck Sharp & Dohme submitted that during interviews it had been concerned to uncover a set of slides (the 'DEXA Placements DIY Guide' provided) prepared by a representative to present to a small number (less than 10) of selected representatives, managers and marketing specialists at a regional meeting, which it believed mischaracterised the DEXA programme and contained suggestions about its operation that Merck Sharp & Dohme believed did not represent the stated policy objectives of the company or what happened in practice. This slide set was prepared contrary to company policy that representatives should not create their own materials and was not submitted for medico-legal vetting. Revised SOPs and a training schedule would ensure as far as possible that this did not happen again. This slide set appeared to have been produced at the same time and possibly by the same person who drafted a 'DXA checklist'.

In summary Merck Sharp & Dohme did not believe the DEXA programme operated between 2000 and 2004 breached the relevant Codes. There was no evidence of any intention to influence the prescribing habits of GPs or to induce them to prescribe a medicine that they would not otherwise have prescribed. However, the provision of this service enhanced patient care and benefited the NHS. There would be patients in whom fractures and other serious effects of osteoporosis had been prevented because they were able to have a DEXA scan which the NHS was otherwise unable to provide.

Special Products Business Unit

Merck Sharp & Dohme submitted that the allegation in this part of the complaint was difficult to make out. The complainant stated that 'the group had not acquired specific evidence of malpractice'. The most coherent interpretation Merck Sharp & Dohme could put on the complaint was that the Special Products Business Unit had made ROI calculations in respect of the provision of unregistered grants.

Merck Sharp & Dohme noted that the complaint was not limited to a particular time period but it had searched the records of the Special Products Business Unit for the last 18 months and had identified only two grants which could be described as 'unconditional', to use the complainant's term. This was not surprising since the provision of unrestricted grants by Merck Sharp & Dohme was exceedingly rare. It was much more common that grants were provided for specific educational or patient care purposes.

Merck Sharp & Dohme provided all documents

relating to these grants and submitted that there was no suggestion that ROI calculations had been made in relation to either of them. Merck Sharp & Dohme had interviewed the employee who led the Special Products Business Unit, and she confirmed that she did not make such calculations in relation to any grants, unrestricted or otherwise.

Migraine Team

Merck Sharp & Dohme submitted that it was unable to discern a specific allegation in relation to this matter. Merck Sharp & Dohme enclosed a set of archived materials relating to the migraine therapy review audits that it offered to GPs between 2000 and 2005 which it submitted were given to representatives, GPs or patients. There were only two external service providers during that time from January 2004 onwards. The documents used by one were amended and re-approved at the end of 2002. The programme was not intended to, and did not in practice, act as an inducement to doctors to prescribe any specific medicine.

Merck Sharp & Dohme submitted that the selection criteria for practices was their willingness to take part in the programme. Representatives from the team responsible for implementing the programme would make GPs aware of the service as a routine part of all promotional calls during which the customer expressed an interest in the treatment of migraine. If there was a positive response the representative would make a separate appointment and return to discuss the service with the materials. The team involved with implementing the programme was small (15 representatives) and their territories were designed to cover only parts of the country where higher than average amounts of any migraine treatment (not specifically Maxalt) were prescribed. There were no proformas used by the representatives responsible for implementing the programme.

PANEL RULING

The Panel noted that the osteoporosis audit took place prior to 2004/05. Thus the 2003 Code applied; the supplementary information to Clause 18.1 of that Code stated that medical and educational goods and services had to enhance patient care or benefit the NHS. The change under Clause 18.4 of the 2006 Code was that such services had to either enhance patient care or benefit the NHS and maintain patient care and they could not be an inducement to sell any medicine. In addition the provision of such goods or services must not be done in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine.

With regard to therapy review services the supplementary information to Clause 18.4 of the 2006 Code provided helpful guidance. A therapeutic review which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The arrangements for therapeutic review must enhance patient care, or benefit the NHS and maintain patient care. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

The supplementary information to Clause 18.1 of the 2003 Code, Provision of Medical and Educational Goods and Services, stated that if representatives provided, delivered or demonstrated medical or educational goods and service then this must not be linked in any way to the promotion of products.

1 DEXA placement in primary care

The Panel considered that the provision of a mobile bone densitometry service would enhance patient care and benefit the NHS. The service had to be provided in such a way as not to be an inducement to prescribe, supply, administer, recommend or buy any medicine (2003 Code).

Fosamax Once Weekly was indicated for the treatment of post-menopausal osteoporosis. Fosamax reduced the risk of vertebral and hip fractures.

The Panel noted that the document 'DEXA placement in Primary Care' stated with regard to appropriate use of DEXA placement that epidemiology suggested that 30% of post-menopausal women were osteoporotic by WHO standards and accordingly of 25 post-menopausal women scanned, statistically 8 would have osteoporotic BMD (bone mineral density). Identification of the highest risk patients would ensure effective utilisation of the technology. The priorities for achieving commercial and personal goals referred to 'Maintain DEXA (market expansion) activities' as a key area for representatives. The project strategy in the briefing document 'Forearm Bone Densitometry' stated that through well researched and rational placement of forearm DEXA technology in the community, co-ordinated through Primary and Secondary Care sectors, Merck Sharp & Dohme would significantly increase the number of patients diagnosed as osteoporotic.

The placement criteria (dated February 2001) stated that to be consistent with the AGO Report, Merck Sharp & Dohme must be seen to be rational in placement of the machines whilst being sensitive to local issues and ensuring that they were used maximally.

The Funding of Osteoporosis Projects briefing document (dated 2002) referred to the project committee consisting of the marketing manager, two national sales managers and two healthcare managers. The document stated that a proposal should include *inter alia* the benefits of the project locally and for Merck Sharp & Dohme. No sales data, ROI, or script impact calculations should be included with the proposal.

A proposal for funding a project was provided and included a section on the prescribing environment. The group being considered for receiving a DEXA machine was said to be currently in the process of updating prescribing guidelines which would include 'Alendronate OW' and would be issued in November 2001. Details of the alendronate market share were provided in the proposal. The date of this proposal was not given. Reference was made to a strategy group meeting on 3 April 2001.

The Panel noted that training slides 'DEXA Placements DIY Guide', provided by Merck Sharp & Dohme, were not approved by the company. According to Merck Sharp & Dohme they had been used with a small group of representatives. No official Merck Sharp & Dohme training slides had been submitted.

The slides provided included one headed 'Identify Surgery' listing the criteria as 'sales data, Fosamax target, speaker meeting, influential contact'. For some reasons representatives were advised on the day that scanning took place to 'beware of staff'. Inclusion details listed, *inter alia*, 'Rx update FOW/DPMO' and 'sales background'. The sales review criteria were listed as 'market potential, market share FOW vs DPMO, market trend, size market and sales per GP'. Support information included 'GP RX intent'.

The DXA checklist, which had also not been authorized by the company, included a list of triggers one of which was that 'GPs are reluctant to start therapy for patients, they believe have osteoporosis without a DXA scan'. Another listed trigger was 'Fosamax is bisphosphonate of choice' , this was emphasised as it was, the only trigger in italics. The outcomes/monitoring included what treatment initiated if any.

The Panel considered that on the information before it there was no evidence that the representatives had been briefed about the need to separate the provision of medical and educational goods and services from the promotion of medicines. The service would be seen by representatives as being linked to the promotion of Fosamax. This would be reinforced to those representatives shown the training slides and given the DXA check list. This was totally unacceptable.

Under the supplementary information to Clause 18.1 of the 2003 Code materials relating to the provision of medical and educational goods and services must be examined by the Code of Practice signatories. This had not happened with regard to some of the materials.

The template letters for patients did not state that the service was sponsored by Merck Sharp & Dohme.

The Panel considered that the programme did not meet the requirements of Clause 18.1 of the Code. The training slides linked the provision of the service to the use of Fosamax. The Panel considered that the arrangements were unacceptable in relation to Clause 18.1 and ruled accordingly. This ruling was appealed.

The Panel considered that high standards had not been maintained and the circumstances brought discredit upon the pharmaceutical industry; breaches of Clauses 9.1 and 2 were ruled. These rulings were appealed.

The Panel decided to report Merck Sharp & Dohme to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

2 Special Products Business Unit

The Panel noted that the complainant acknowledged that he did not have specific evidence of malpractice and it appeared that ROI calculations were made regarding grants to specialist hospital units. Merck Sharp & Dohme could only identify two unconditional grants which it submitted was not unexpected as the company rarely gave unconditional grants. More commonly the company gave grants for specific purposes. The business unit manager did not make such calculations in relation to grants unrestricted or otherwise.

The paperwork provided by Merck Sharp & Dohme related to two grants to hospitals. One was an educational grant of £10,000 and the other was for £1,000 for developments in a cardiac care unit. There was no evidence that ROI calculations had been made.

The Panel considered that there was no evidence that Merck Sharp & Dohme had included ROI calculations in relation to grants. Thus no breach of Clauses 18.1, 9.1 and 2 was ruled.

3 Migraine Team

The Panel noted that the complainant was not clear whether the switch/upgrade programmes intended to support a change from Imigran to Maxalt were at odds with the Code. The complainant had not given any details of his/her specific concerns in this regard.

The material supplied by Merck Sharp & Dohme set out the arrangements for a number of migraine therapy review services offered in 2001, 2003 and 2004 onwards. If a practice decided to proceed with such a review a pre-agreed service specification would be signed which was flexible to suit the needs and prescribing habits of the practice. The practice could specify which patients should be included/excluded and set its own preferred treatment algorithm. The doctor was responsible for deciding whether to implement any change in therapy.

It appeared that all of the materials had been seen by the company. The materials did not feature the Maxalt product logo and rarely even used the product name. The Panel noted that a bar chart depicting the percentage of patients with 2 hour headache response did feature the Maxalt product name but the Panel did not consider that such use was sufficient to render the material in breach of the Code. There was no representatives' briefing material *per se* provided. On the basis of the material before it there was no evidence that the migraine therapy review was intended to support a switch from Imigran to Maxalt as alleged. No breach of Clauses 18.1, 9.1 and 2 was ruled.

APPEAL BY MERCK SHARP & DOHME

Merck Sharp & Dohme appealed the Panel's rulings of breaches of Clauses 2, 9.1 and 18.1 of the 2003 Code with regard to its funding of a community based service in support of the diagnosis of osteoporosis between 2000 and 2004.

Merck Sharp & Dohme submitted that the factual findings of the Panel on which the rulings of breaches of the Code were made were not the basis for the original complaint. The Panel's ruling on the allegation of a breach of Clause 18.1 of the 2003 Code stated that: the Panel did not have before it evidence that representatives had been briefed about the need to separate the provision of medical and educational goods and services from the promotion of medicines; and the materials relating to the DEXA service had not been reviewed; and the training slides linked the provision of the DEXA service to use of Fosamax; and the template letters for patients did not state that the service was sponsored by Merck Sharp & Dohme.

Merck Sharp & Dohme acknowledged that it was unable to provide the Panel with formal representatives' training material that it could demonstrate had been examined by Code signatories. This should not be surprising since the DEXA service was launched six years ago, when the applicable Code was the 1998 Code. Pursuant to the 1998 Code, there was a requirement to train representatives on the technical aspects of the medicines they were promoting. The evidence from the 'DEXA placement in primary care' document previously provided to the Panel amply demonstrated that such technical training took place. There was no requirement under the 1998 Code, nor was there now, to preserve the evidence of such certification for more than three years. Therefore, it was particularly harsh that the Panel found Merck Sharp & Dohme in breach of the 2003 Code, which could not on any view have been the applicable Code for a service which began in 2000, and, in any event, for a failure to preserve training materials which, under any Code, were not required to be preserved for such a length of time.

Moreover, all of the representatives recently interviewed described training on the DEXA service in one form or another. Some thought there might have been a presentation at a regional meeting, others merely recalled this aspect being emphasised in informal mentoring by managers or other representatives. In any event, since the representatives had little to do with the service after providing the first contact details for the radiographers, it was not a difficult task needing constant reinforcement to separate the provision of the service from promotion. There was no opportunity to promote products once the service had been introduced. Recent interviewees confirmed this and also confirmed that they usually introduced the service in a separate non-promotional phase at the end of a promotional call, often in response to an unprompted observation from a GP about the lack of diagnostic facilities. In other cases, the representative might simply have noted an enquiry about the service and dropped the contact details off with the practice manager at another non-promotional visit. In some cases, the service was introduced after educational speaker meetings on osteoporosis and in others the coordination was provided by a secretary to the local consultant rheumatologist [sic] to whom the representative delivered details of radiographers available to provide screening.

Given employees' recollections that training had been given, Merck Sharp & Dohme submitted that, had it had an opportunity to submit its evidence on this point, the Panel could not have reached the conclusion that it did on the absence of evidence of training.

Merck Sharp & Dohme submitted that the Panel had misunderstood some of the materials submitted in its original response. The Panel's reference to the training slides in its ruling appeared to refer to the 'DEXA Placements DIY Guide', submitted in response to the complaint. Merck Sharp & Dohme accepted that these slides contained statements suggesting that surgeries were identified by sales data and that the representative might play a greater role in the service than any of its employees recalled was the case. However, the Panel was wrong to describe these as training materials. These were unauthorised documents produced in unclear circumstances by an unknown person or persons. No evidence was found that these materials were used in presentations or were otherwise used in training. They were disclosed as Merck Sharp & Dohme could not exclude the possibility that they were shown to a small number of representatives, and they were, therefore, responsive to the Panel's original request but it did not disclose them or describe them as training slides. In fact, the materials that Merck Sharp & Dohme produced and which clearly were representative training materials, specifically the Dexa Placement in Primary Care letter and the Forearm Bone Densitometry briefing document, made no such linkage. At least one of Merck Sharp & Dohme's recently interviewed representatives recalled representatives specifically being trained at a meeting using these slides.

Merck Sharp & Dohme was as certain as it could be that the 'DEXA Placement DIY Guide' was not used as formal training material and there was no evidence to the contrary. The Panel's ruling on that issue should not stand.

Failure to disclose Merck Sharp & Dohme's sponsorship on template letters was another issue that was not raised by the complainant. Merck Sharp & Dohme did not deny the findings of the Panel on this issue but it questioned whether this finding, on its own, would merit a ruling of a breach of Clause 18.1. It seemed very unlikely to justify a ruling of breach under Clauses 9.1 or 2.

The Panel did not make any rulings which upheld the complainant's allegations. The complainant made specific factual allegations relating to the forearm DEXA service offered to GPs by Merck Sharp & Dohme. Merck Sharp & Dohme had in its response effectively rebutted each element of the complaint. The specific factual allegations were that: representative colleagues employed within the FROSST division at the time had informed the group that they were required to manage this programme from start to end; sales metrics were considered when decisions were made regarding which practices

should be offered the scanners and representatives were required to input into the company's ETMS the number of patients that went on Merck's medicine Fosamax as a result of their scan.

Merck Sharp & Dohme had interviewed two representatives who had been on the FROSST team in 2000, when the service was introduced, and also the then national marketing manager and the then national sales manager. The evidence of all four employees, the two most senior of whom it had named, and on which it relied in its response to the complaint, unanimously rejected each allegation.

Merck Sharp & Dohme submitted that it had described in detail what role the representatives played in relation to the offer made to GPs. The offer was limited to just that, and Merck Sharp & Dohme noted that it was often made in response to an unsolicited enquiry from GPs lamenting the lack of osteoporosis diagnostic facilities in their, usually rural, practice areas. Merck Sharp & Dohme stated that it had found no evidence to support the allegations. Specifically, while representatives managed some of the administrative arrangements for the programme, the medical and technical aspects were left entirely to the radiographer.

Merck Sharp & Dohme noted that no documents were provided by the anonymous complainants to support their allegations, nor was it possible for the Authority to request further documents from them, either to support or undermine the allegations. Merck Sharp & Dohme provided examples of presentations made to representatives by managers, specifically the document 'DEXA Placement in Primary Care' and the document entitled 'Forearm Bone densitometry – briefing document'. The first document did not refer to any role to be played by the representative in relation to the service because all the representatives typically did was give the contact details of a radiographer to either the GP or practice manager and leave them to arrange suitable dates, times and lists of patients between them. The representatives would have checked, as a matter of courtesy, that the arrangements ran smoothly, but the evidence was that there was little more for them to do, once the service had been introduced. The 'Osteoporosis Audit and DEXA Scanning Programme' documents, which illustrated what happened at the individual practice level, supported this.

This was the best evidence available and was supported by evidence of five further representatives or former representatives involved in the offer of DEXA services and a manager, whom Merck Sharp & Dohme had now been able to identify and with whom it had spoken. Merck Sharp & Dohme offered to supply the names of all the representatives and managers it had interviewed, and, if necessary, the names of radiographers who provided the service and GPs who took it up. Merck Sharp & Dohme was confident that the evidence of its representatives was completely consistent. Merck Sharp & Dohme could not, therefore, see the basis upon which it could be said that the first allegation was proved, either on a balance of probabilities or beyond reasonable doubt. This conclusion was borne out by the fact that the Panel in its ruling made no finding of fact in relation to this allegation.

Merck Sharp & Dohme submitted that a similar pattern emerged when the second factual allegation was examined in relation to the evidence. The oral evidence of Merck Sharp & Dohme's employees supported its defence that sales metrics were not considered when decisions were made about where to place services. There was simply no evidence to the contrary, either documentary or oral testimony capable of being tested, on which the Panel could reach a different conclusion. Indeed, Merck Sharp & Dohme noted that the Panel had not made a ruling in relation to this allegation. Merck Sharp & Dohme explained in its response that in most cases there would be little or no prescribing of any osteoporosis treatments without a DEXA scanning facility because GPs were unable to reliably diagnose the condition.

Merck Sharp & Dohme submitted that the evidence considered by the Panel in relation to the third allegation was similarly uniformly in its favour. This allegation that data relating to sales generated by the DEXA service was entered onto the ETMS was entirely unsupported by documentary evidence or testable oral evidence. There appeared to be no field in the ETMS which such sales metrics could be entered. None of the employees interviewed recalled entering such data themselves and this was confirmed by recent interviews. Merck Sharp & Dohme had also identified some slides used for training representatives on the DEXA service in 2003 that described how information should be entered on the ETMS (copies of which were provided). Merck Sharp & Dohme noted that there was no reference to entering sales metrics. The credibility of the anonymous complainants must be seriously undermined by these findings. The Panel might already consider them to be less than reliable witnesses, their having mistaken the date the DEXA service started by two years. The anonymous complainants stated that the service began in 2002, when it in fact began in 2000, as was demonstrated by the documents referred to in the Panel's ruling, some of which dated from 2000 and 2001. At the very least this suggested that the complainants' informants (and it was clear that the complaint consisted essentially of anonymous second hand evidence not within the knowledge of the complainants) were not so closely involved in the DEXA service as to be properly aware of when it was introduced. There was no basis on which their evidence should be preferred to Merck Sharp & Dohme's evidence. The Panel had not made a ruling on the third allegation.

In summary, therefore, the great weight of evidence contradicted the anonymous allegations and, in any event, the Panel did not make a factual ruling in relation to any of the allegations. This could not lead to a finding of a breach of Clause 18.1.

The complainants' allegation of a breach of Clause 18.1 flowed directly from their three factual allegations and was dependent on their being made out, which they had not. This was demonstrated by the complainants' use of the word 'Accordingly …' to link the factual allegations and the aspect of the Code to which they stated the facts related.

Merck Sharp & Dohme submitted that at most, there was evidence that it had failed to disclose its

sponsorship on the template service letters, and that one, perhaps two, of its employees had created certain materials which, while not Code compliant, had little if any circulation within Merck Sharp & Dohme and were certainly not authorized by it. Neither set of facts appeared to fulfil the necessary elements of a breach of Clause 18.1, which was one of the most serious breaches of the Code. The Panel had not found that gifts, benefits in kind or pecuniary advantages had been offered or given to members of the health professions or to administrative staff as an inducement to prescribe, supply, administer, recommend, buy or sell Fosamax. The DEXA service was a service to patients. It offered no advantage, pecuniary or otherwise to GPs or their staff and was not promotional either in conception or delivery. The breaches ruled by the Panel in relation to the absence of logos and absence of evidence of training materials on the need to distinguish between promotion and the provision of services did not appear to justify a breach of Clause 18.1, particularly when evidence of its employees rebuted the presumption that, because no written materials could be produced from over three years ago, no training had taken place.

If the elements of a breach of Clause 18.1 of the 2003 Code were not made out then it must follow that there could have been no breach of Clauses 2 or 9.1. Even if the failure to produce evidence of written training materials and to include a logo on the patient letter was a breach of Clause 18.1, Merck Sharp & Dohme questioned whether these were sufficiently grave to justify rulings of a breach of Clauses 9.1 and 2. Merck Sharp & Dohme also asked whether an isolated disclosure of one unauthorised set of slides dating from over 5 years ago, whose authorship and provenance could not be precisely determined, that might, at most, have been seen by a handful of representatives whose subsequent oral evidence was that they did not lead to their linking the provision of the service with promotion of Fosamax, should lead to a ruling of a breach of Clause 2, when all the other evidence pointed to Merck Sharp & Dohme's official training on the programme and delivery of it having been Code compliant.

In the light of its submissions Merck Sharp & Dohme concluded that: it was clear on the face of the ruling that the factual allegations in the complaint were not made out; an adverse ruling had been made by the Panel in relation to alleged breaches which were not put to Merck Sharp & Dohme; the wrong version of Code had been used to justify a finding of breach and the finding of breach appeared to relate to an inability to produce documentary evidence of appropriate training from six years ago, when no version of the Code required training material to kept for more than three years.

Merck Sharp & Dohme thus submitted that the Panel's ruling in relation to breaches of Clauses 2, 9.1 and 18.1 of the 2003 edition of the Code should be set aside by the Appeal Board.

APPEAL BOARD RULING

The Appeal Board noted Merck Sharp & Dohme's submission that the purpose of the DEXA programme was to expand the diagnosed population of osteoporotic patients. The programme had started to wind down in the latter half of 2003 and so no new representatives were trained from this point; only those already trained and experienced on the programme continued to work on it. Managers had continued to provide some training by mentoring in the field. Merck Sharp & Dohme's representative explained that this was one of the reasons for the lack of available training documentation concerning the DEXA programme. Nonetheless, the Appeal Board considered that the company should have been able to produce job bags for the relevant training material which governed the representatives' activities from the latter part of 2003 onwards.

The Appeal Board noted that the company was able to provide little evidence about the provenance, status and use of the 'DEXA Placements DIY Guide' and the 'DEXA checklists' which it submitted were found on the computer of an existing employee who had worked on the DEXA programme. That employee did not write either document. The Appeal Board was alarmed at the 'DEXA Placements DIY Guide' and concerned that anyone could have produced it. The company's investigation indicated that the 'Guide' had been discussed at a best practice meeting typically attended by one representative from each of the six sales regions and four regional managers. The basis of the discussion and its outcome were not known. There was no evidence that the material had formed part of any representatives' training for the DEXA service. The Appeal Board considered that there was no evidence on the balance of probabilities that the material 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.

The Appeal Board further noted another document 'Guide to Proposal Development' which related to funding for osteoporosis selective case finding in primary care. Under a heading of 'Benefits of the project' was stated 'Environment positive for Fosamax with high market share in locality and inclusion in clinical guidelines'. The Appeal Board was concerned at this statement but noted that Merck Sharp & Dohme's representatives stated that to the best of their knowledge no proposals had ever taken place, nor was there any evidence that the document had influenced representatives' behaviour.

The Appeal Board understood why the Panel was concerned about the material. However, it considered that the complaint had not established on the balance of probabilities that the arrangements amounted to a breach of Clause 18.1 of the Code. Thus the Appeal Board ruled no breach of Clause 18.1 and hence no breach of Clauses 9.1 and 2.

The Appeal Board noted the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure. The Appeal Board noted its comments above and its rulings of no breach of the Code. The Appeal Board decided to take no further action.

Complaint received **30 June 2006**

Case completed **22 November 2006**