CASE AUTH/1814/3/06

FORMER EMPLOYEE v MERCK SHARP & DOHME

Nurse audit programme

A former sales representative, writing under a pseudonym, complained about a nurse audit disease management programme offered by Merck Sharp & Dohme and delivered by a service provider. The complainant referred to this as the Hypertension Review Programme Supportive of the GMS Contract (HRP-GMS).

The complainant stated that the HRP-GMS programme had been in operation from 2004 to the present day. Throughout this time, Merck Sharp & Dohme's representatives involved in the first-line promotion of Cozaar (losartan) had been given primary responsibility for identifying surgeries that were to be offered nurse advisors from the service provider to undertake audits relating to hypertension and Type 2 diabetes. The stated goals of the HRP-GMS were to improve patient management and support practices to achieve GMS contract targets in these disease areas.

The complainant was concerned about the way in which representatives and their managers had to select surgeries to be considered for placement of a nurse advisor. In this regard the complainant noted that the hypertension and Type 2 diabetes proformas explicitly referred to a number of sales and prescribing behaviour metrics to be fulfilled before a particular surgery was offered the service. The complainant understood that this was in breach of the Code as services to medicine and product promotion must not be linked in any way. An email from a senior manager in the Cozaar team, and a slide presentation entitled 'COZAAR Nurse Audit Programme', showed that representatives and their managers were required to complete the proformas in order to secure placements.

The complainant stated that he had raised his concerns with several superiors within Merck Sharp & Dohme but repeatedly failed to receive a substantive answer to questions.

The complainant also alleged that Merck Sharp & Dohme representatives were set annual objectives which required them to call on target doctors up to six times within a six month period. The complainant and other colleagues raised this issue with line managers to be told that call frequency must be elevated during a launch phase and that representatives must use their acumen to circumvent the restrictions imposed by the Code.

The Panel noted Merck Sharp & Dohme's submission that there were differences between the slides sent by the complainant and the Cozaar nurse audit programme briefing slides used by the company to train the representatives. The Panel noted that the training slides, as provided by Merck Sharp & Dohme, were branded with the Cozaar logo. The first slide referred to the 'COZAAR Nurse Audit Programme'. The service would thus be seen by representatives as being linked to the promotion of the product. No mention was made in the presentation of the need to separate the provision of medical and educational goods and services from the promotion of medicines. This was totally unacceptable.

The slides provided by Merck Sharp & Dohme included instructions that the audit service was only to be offered to practices that, *inter alia*, had 'Strong buy into LIFE and COZAAR messages'. Surgeries had to agree to Cozaar as the medicine of choice in relation to 'A' as set out in the British Hypertension Society (BHS) guidelines where A meant ACE inhibitor or angiotension antagonist. The practice also had to have a 'call rate of 6 prior to audit plus speaker meeting attendance'. The surgeries selected must have target doctors as project lead. The programme was referred to as a targeted resource to influence the environment.

The aim of the programme was to provide practices with an independent nurse advisor to review all uncontrolled hypertensive patients over 55 in order to improve blood pressure management in accordance with the ABCD goal (this was taken to be a reference to the BHS guidelines). The programme aims included the benefits of restoring blood pressure to normal or optimum levels, enhanced patient education through detailed lifestyle advice and the update of existing practice registers.

The slides headed 'The program guidance form' had 'Cozaar/Losartan' printed in a box beneath the heading 'Practice Policy – please complete'.

Another slide provided by Merck Sharp & Dohme was headed 'Implementation changes' and referred to a more focussed proforma for both programmes. This was shown on the following slide which made it clear that if the practice angiotensin antagonist of choice was not Cozaar then the practice was not suitable. If the practice had not agreed to Cozaar as the drug of choice for A in the BHS guidelines ABCD then it was not suitable. If the brick market share was not above 40% for Cozaar then the practice was not suitable. The proforma provided by the complainant was similar to that shown on the slides; it additionally included a section asking the representative for the rationale as to why it was important to nominate the surgery for the audit.

The medical/legal approved proformas provided by Merck Sharp & Dohme, however, were very different to those on the slides and those provided by the complainant; there were different questions to be completed and there were no criteria to be met for the practice to be deemed suitable for offering the service.

The HRP-GMS Protocol provided by the complainant referred to the BHS recommendations for combining blood pressure lowering medicines. It included the reference to A as 'angiotension receptor blocker or ACE inhibitor'; this matter was the subject of complaint in Case AUTH/1762/10/05 and the Panel considered that Merck Sharp & Dohme should have changed the protocol as a result of the ruling in that case.

The Panel noted that the practice had to agree each stage of the process. Hypertensive patients were invited for review by the nurse if they were over 55 and had not achieved national audit targets, ie blood pressure higher than 150/90, and had been on current treatment for at least six weeks prior to assessment. The nurse would then put patients into one of three registers: those appropriate for medication review according to the HRP-GMS as directed by the GP; those appropriate for medication review by the practice (ie not at target but less than 55 years old) and the third for those inappropriate for medication review as directed by the GP. The Panel queried how the second register would come about given that the inclusion criterion was for patients over 55.

The audit proposal form appeared to go beyond the inclusion and exclusion criteria. The practice prescribing policy had to be entered on a form which also reproduced the incorrect version of the BHS guidelines. The form was to be signed by some of the practice doctors.

The template letter for patients regarding the audit did not state that the audit was sponsored by Merck Sharp & Dohme.

The Panel considered that the Merck Sharp & Dohme training slides clearly associated the programme with the promotion of Cozaar by use of logos and the introductory slide. The amendments to the proformas clearly linked the nurse audit programme to the use of Cozaar. The Panel considered that the arrangements were unacceptable and ruled a breach of the Code.

The Panel considered that 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.

With regard to the allegation about call rates, the Panel noted Merck Sharp & Dohme's submission that the two sales forces together were expected to have either seven or five contacts with target customers each year (depending on whether they were primary or secondary targets). In total this meant each representative would have either four or three contacts with primary target doctors or two or three contacts with secondary target doctors. Such contacts included all occasions on which a representative met a customer. The Panel noted that the annual objectives did not appear to be included in the sales incentive scheme 2005 documents. The Panel noted that there was a discrepancy between the complaint and the response in this regard. The Panel considered that there was no evidence to show that representatives were encouraged to make six calls in six months as alleged. No breach of the Code was ruled.

The Appeal Board was extremely concerned that the arrangements for the audit programme had highlighted very serious deficiencies in Merck Sharp & Dohme's procedures including the copy approval system. Given the significant investment that the audit represented the Appeal Board considered that it was inconceivable that it was not more tightly controlled; material had been used which had not been approved. The service had been clearly linked to the promotion of Cozaar and there appeared to be a serious lack of control by senior managers. The Appeal Board considered that the arrangements were totally unacceptable.

With regard to the Panel's ruling that the circumstances brought discredit upon the pharmaceutical industry, the Appeal Board was concerned that Merck Sharp & Dohme's actions had the potential to compromise patient safety by inappropriate prescribing. Further, Merck Sharp & Dohme's actions would undermine both prescribers' and patients' confidence in the provision of properly conducted services. The Appeal Board was extremely concerned that some Merck Sharp & Dohme staff had not realised that the amended proformas and the slides used as training material were totally unacceptable in relation to the requirements of the Code.

The Appeal Board considered that this was an extremely serious case.

The Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an immediate audit of Merck Sharp & Dohme's procedures. In addition, Merck Sharp & Dohme would be publicly reprimanded and required to issue a corrective statement. In accordance with Paragraph 12.1 of the Constitution and Procedure, the Appeal Board decided to report the company to the ABPI Board of Management with the recommendation that it be suspended from membership of the ABPI.

Upon receipt of the audit report and Merck Sharp & Dohme's comments upon it, the Appeal Board noted that the company had started to implement the recommendations and address the observations set out in the audit report. This would take some time given that the problems were institutional in nature and many changes were necessary.

The Appeal Board decided that Merck Sharp & Dohme should be reaudited later in the year.

The ABPI Board of Management noted the audit report and Merck Sharp & Dohme's comments upon it.

It was noted that the Appeal Board had recommended that Merck Sharp & Dohme be suspended from membership of the ABPI. It was further noted that Merck Sharp & Dohme was to undergo a second audit of its procedures, that the company was to be publicly reprimanded and that Merck Sharp & Dohme had issued a corrective statement. The ABPI Board noted that Merck Sharp & Dohme had fully accepted responsibility for the matters giving rise to the complaint and that current management, including the new managing director, was taking action to ensure that there was no repeat: action which ranged from training through to changes in culture.

Nevertheless, given the serious nature of the case, the ABPI Board decided to suspend Merck Sharp &

Dohme from membership of the ABPI for a minimum of three months, commencing 2 October 2006, after which time the situation would be reassessed. The ABPI Board requested it see a copy of the report for the second audit.

A former sales representative of Merck Sharp & Dohme Limited, writing under a pseudonym, complained about a nurse audit programme offered by Merck Sharp & Dohme and delivered by a service provider. The complainant referred to this as the Hypertension Review Programme Supportive of the GMS Contract (HRP-GMS).

COMPLAINT

The complainant stated that the HRP-GMS programme had been in operation and supported by Merck Sharp & Dohme from 2004 to the present day. Throughout this time, Merck Sharp & Dohme's representatives involved in the first-line promotion of Cozaar (losartan) had been given primary responsibility for identifying surgeries that were to be offered nurse advisors from a service provider to undertake audits relating to hypertension and Type 2 diabetes. The stated goals of the HRP-GMS were to improve patient management and support practices to achieve GMS contract targets in these disease areas.

The complainant understood from the previous and current editions of the Code that representatives could introduce general practices to company sponsored disease management programmes, as long as this was done in a non-promotional call. However, his concerns about the conduct of this programme related to the way in which representatives and their managers had to select those surgeries to be considered for placement of a nurse advisor. In this regard the complainant noted that the hypertension and Type 2 diabetes proformas explicitly referred to a number of sales and prescribing behaviour metrics to be fulfilled before a particular surgery was offered the service. The complainant understood that this was in breach of the letter and spirit of the Code which mandated that services to medicine and product promotion must not be linked in any way. An email from a senior manager in the Cozaar team, and the slide presentation entitled 'COZAAR Nurse Audit Programme' showed that representatives and their managers were required to complete the proformas in order to secure placements.

The complainant's motive for making the Authority aware of these issues was to establish the correctness, or not, of the conduct of this programme. Having taken the ABPI representatives examination, the complainant believed that he was individually accountable for adherence to the Code at all times and in the event that he observed behaviour that appeared to contravene the Code was duty bound to seek guidance from the Authority to rectify the matter. He had raised his concerns with several superiors within Merck Sharp & Dohme but repeatedly failed to receive a substantive answer to questions. In light of the company's avowed ethical stance the complainant felt frustrated and powerless to address this issue through internal company channels.

The complainant knew that Merck Sharp & Dohme was recently found in breach of the Code in relation to the inaccurate representation of the British Hypertension Society (BHS) guidelines. This, combined with another concern about representatives being set call frequency targets that appeared to be in breach of the Code, had left him no option but to raise these points directly with the Authority. Specifically, Merck Sharp & Dohme sales representatives were set annual objectives which required call frequencies on so-called target doctors up to six times within a six month period. The complainant stated that he and other colleagues raised this issue with line managers to be told that call frequency must be elevated during a launch phase and that representatives must use their acumen to circumvent the restrictions imposed by the Code.

When writing to Merck Sharp & Dohme, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.4 and 18.4 if the 2006 edition of the Code applied or, if the 2003 edition applied, then Clauses 2, 9.1, 15.4 and 18.1, paying particular attention to the supplementary information to Clause 18.1.

RESPONSE

Merck Sharp & Dohme stated that as the relevant documents pre-dated September 2005, the 2003 edition of the Code applied.

Merck Sharp & Dohme dealt with the complaint in three elements.

1 The nurse audit

This was a nurse audit programme offered by Merck Sharp & Dohme and delivered by a service provider. Two audits were available; one in hypertension and one in Type 2 diabetes. GPs were offered the audit by a Merck Sharp & Dohme sales force. If the GP was interested in taking up the offer, the representative filled in a form, which was approved by their manager and by the Cozaar marketing team which authorized the service provider to offer the audit to that surgery. A nurse auditor from the service provider then contacted the practice directly and thereafter the Merck Sharp & Dohme representatives had no further involvement in the delivery of the audit itself. The audit was conducted by the nurse, working on behalf of the service provider, in conjunction with the practice and Merck Sharp & Dohme had no further involvement.

The nurse audit was originally offered in 2004 on a small pilot basis in hypertension, Type 2 diabetes and hypercholesterolaemia. The pilots proved successful and so, in 2005, they were rolled out nationally. The complainant had attached a number of documents relating to the audit:

a) Hypertension review programme protocol

This document was fully reviewed within Merck Sharp & Dohme which believed it complied with the Code, save that the BHS Guidelines on the Management of Hypertension contained the footnote 'A: Angiotensin receptor blocker or ACE Inhibitor' whereas the guidelines had these treatments options the other way round. This had been the subject of Case AUTH/1762/10/05.

b) Nurse booking form

So far as Merck Sharp & Dohme could tell, this was a document provided by the service provider to its nurse auditors. Accordingly, this document was not reviewed by Merck Sharp & Dohme. It nonetheless believed that it complied with the relevant provisions of the Code.

c) Email dated 28 July 2005 from a senior manager in the Cozaar team

This was a communication from the Cozaar marketing team to the relevant sales forces offering the audit to doctors. As noted by the complainant, this email referred to 'a good increase in the number of proformas coming through again this week' (please see below). Unsurprisingly given the nature of the document, it was not reviewed internally. Nonetheless, Merck Sharp & Dohme believed that in all other respects it complied with the Code.

d) Cozaar nurse audit programme briefing slides

Merck Sharp & Dohme was unable to identify the slide presentation. A slide presentation was used at the launch of the audit to the sales forces and whilst the slide set supplied by the complainant contained some of those slides it appeared to have a number of additional ones as well. As the complaint was anonymous, Merck Sharp & Dohme was unable to identify who created this precise presentation. It did, however, agree with the complainant that the slide presentation referred to the proformas and indicated that they should be completed by representatives and sent to the Cozaar marketing team.

e) Hypertension and Type 2 diabetes proformas

Merck Sharp & Dohme stated that these documents were created by the Cozaar marketing team and circulated to the relevant sales forces offering the nurse audit programme. [At the audit it became apparent that the proformas at issue had been used in the pilot project which was organised by another business unit before being handed to the cardiovascular business unit for rollout.] They were not reviewed internally and Merck Sharp & Dohme believed that they breached Clause 18.1 of the Code. Merck Sharp & Dohme apologised for this; once an internal investigation into the matter was complete, disciplinary action would be taken if appropriate.

For completeness sake, Merck Sharp & Dohme noted that some of the material relating to the nurse audit was re-approved in September 2005. At this stage, the relevant proformas were fully reviewed. Copies of the proformas currently being used by its representatives were provided.

2 Whistle-blowing

Merck Sharp & Dohme stated its policy was to take all allegations of breaches of the Code extremely seriously. It was thus surprised and disappointed to note that the complainant's attempt to raise his concerns with his superiors did not result in a thorough investigation of the matter.

As the complaint was anonymous, Merck Sharp & Dohme could not take this matter further. If the complainant was willing to identify himself and the superiors spoken to, Merck Sharp & Dohme would undertake a full investigation.

3 Annual call objectives

Merck Sharp & Dohme stated that as the complainant was anonymous it was unable to respond in detail to the particular allegations that had been made. However, it set out its general expectations of representatives in terms of frequency of contacts with GPs.

The 2005 Sales Incentive Scheme for the two sales forces offering the nurse audit (Chibret and Falcon) set out various targets and the level of bonus which they could expect to receive for various levels of achievement against those targets. The relevant information ('Quarterly Coverage') was set out in detail in each document. Each representative was assigned a number of target GPs on their territory who they were expected to see during the course of a year. Merck Sharp & Dohme provided details of the percentage of target customers to be seen in quarters 1, 2, 3 and 4 to achieve maximum bonus. In addition, they received a team bonus based on the percentage of target customers that the two representatives working on that territory (Chibret or Falcon, as appropriate) saw during the year between them, as a joint activity objective. The relevant figures for the entire teams were 70% in quarter one, 90% in quarter two and 80% in quarters three and four. It should be noted that 'see' included all occasions on which a representative met a customer ie not only pre-arranged visits but also group meetings or visits in response to a specific enquiry from the customer. All representatives had to pass the ABPI examination for medical representatives, as set out in their terms and conditions of employment. Merck Sharp & Dohme therefore expected its representatives to know the requirements of the supplementary information to Clause 15.4 when contacting customers, and indeed this was reinforced to them verbally by their managers.

The annual objectives for representatives in these two sales forces for 2005 required that between them they saw either seven or five target customers each year (depending on whether they were a primary or secondary target). Accordingly, a representative in either Chibret or Falcon would be expected to liaise with their counterpart on the same territory in the other field force to ensure that, between them, they saw at least seven or five target customers per year.

While Merck Sharp & Dohme believed this was clear to its representatives, in light of a number of Appeal Board decisions on this topic in 2005, the two 2006 Sales Force Incentive Schemes specifically reminded representatives of the requirements of the supplementary information to Clause 15.4.

Merck Sharp & Dohme believed that it was clear, therefore, that the annual objectives for each of its representatives required them to see either four or three primary target doctors (or see three or two secondary target doctors). In addition, these contacts

must be made in accordance with the supplementary information to Clause 15.4 of the Code. Merck Sharp & Dohme was, therefore, unable to understand why the complainant believed that they were required to visit target doctors 'up to six times within a six month period'. In addition, Merck Sharp & Dohme noted that under no circumstances should managers ever encourage representatives to 'use their acumen to circumvent the restriction imposed by the Code'. Again, if the complainant was willing to identify himself and the manager in question, Merck Sharp & Dohme would investigate the matter fully. It believed, however, that both the objective for its representatives and the Sales Force Incentive Schemes complied with the Code both in letter and spirit.

PANEL RULING

The Panel noted Merck Sharp & Dohme's submission that the relevant documents predated September 2005. Thus the 2003 edition of the 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.

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 results 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 Panel noted Merck Sharp & Dohme's submission that there were differences between the slides sent by the complainant and the Cozaar nurse audit programme briefing slides used by the company to train the representatives. The Panel noted that the training slides for representatives, as provided by Merck Sharp & Dohme, were branded with the Cozaar logo. The first slide referred to the 'COZAAR Nurse Audit Programme'. The service would thus be seen by representatives as being linked to the promotion of the product. No mention was made in the presentation of the need to separate the provision of medical and educational goods and services from the promotion of medicines. This was totally unacceptable.

The slides provided by Merck Sharp & Dohme included instructions that the audit service was only to be offered to practices that, *inter alia*, had 'Strong buy into LIFE and COZAAR messages'. Surgeries had to agree to Cozaar as medicine of choice in relation to 'A' as set out in the British Hypertension Society (BHS) guidelines where A meant ACE inhibitor or angiotension antagonist. The practice also had to have a 'call rate of 6 prior to audit plus speaker meeting attendance'. The surgeries selected must have target doctors as project lead. The programme was referred to as a targeted resource to influence the environment.

The aim of the programme, as set out in the slides provided by Merck Sharp & Dohme, was to provide practices with an independent nurse advisor to review all uncontrolled hypertensive patients over 55 in order to improve blood pressure management in accordance with the ABCD goal (this was taken to be a reference to the BHS guidelines). The programme aims included the benefits of restoring blood pressure to normal or optimum levels, enhanced patient education through detailed lifestyle advice and the update of existing practice registers.

The slides headed 'The program guidance form' had 'Cozaar/Losartan' printed in a box beneath the heading 'Practice Policy – please complete'.

Another slide provided by Merck Sharp & Dohme was headed 'Implementation changes' and referred to a more focussed proforma for both programmes. This was shown on the following slide which made it clear that if the practice angiotensin antagonist of choice was not Cozaar then the practice was not suitable. If the practice had not agreed to Cozaar as (A) drug of choice in ABCD then it was not suitable. If the brick market share was not above 40% for Cozaar then the practice was not suitable. The proforma provided by the complainant was similar to that shown on the slides; it additionally included a section asking the representative for the rationale as to why it was important to nominate the surgery for the audit.

The medical/legal approved proformas provided by Merck Sharp & Dohme, however, were very different to those on the slides and those provided by the complainant; there were different questions to be completed and there were no criteria to be met for the practice to be deemed suitable for offering the service.

The HRP-GMS Protocol provided by the complainant referred to the BHS recommendations for combining blood pressure lowering medicines. It included the reference to A as 'angiotension receptor blocker or ACE inhibitor'; this matter was the subject of complaint in promotional material in a previous case, Case AUTH/1762/10/05. The Panel considered that Merck Sharp & Dohme should have changed the protocol as a result of the ruling in the previous case.

The Panel noted that the practice had to agree each stage of the process. Hypertensive patients were invited for review by the nurse if they were over 55 and had not achieved audit targets set in the nGMS (blood pressure higher than 150/90) and had been on current treatment for at least six weeks prior to assessment. The nurse would then create three registers: one for patients appropriate for medication review according to the HRP-GMS as directed by the GP; the second for patients appropriate for

medication review by the practice (ie not at target but less than 55 years old) and the third for patients inappropriate for medication review as directed by the GP. The Panel queried how the second register would come about given that the inclusion criterion was for patients over 55.

The audit proposal form appeared to go beyond the inclusion and exclusion criteria. The practice prescribing policy had to be entered on a form which also reproduced the incorrect version of the BHS guidelines. The form was to be signed by some of the practice doctors.

The template letter for patients regarding the audit did not state that the audit was sponsored by Merck Sharp & Dohme.

The Panel considered that the nurse audit programme did not meet the requirements of Clause 18.1 of the Code. The Merck Sharp & Dohme training slides clearly associated the programme with the promotion of Cozaar by use of logos and the introductory slide. The amendments to the proformas clearly linked the nurse audit programme to the use of Cozaar. The Panel considered that the arrangements were unacceptable in relation to Clause 18.1 and ruled accordingly.

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.

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.

The Panel noted that the complainant had further alleged that Merck Sharp & Dohme required representatives to call upon target doctors up to six times within a six month period.

The Panel noted Merck Sharp & Dohme's response which stated that the two sales forces together were expected to see either seven or five target customers each year (depending on whether they were primary or secondary targets). In total this meant each representative would see either four or three primary target doctors or two or three secondary target doctors. Merck Sharp & Dohme had submitted that 'seeing' included all occasions on which a representative met a customer. The Panel noted that the annual objectives did not appear to be included in the sales incentive scheme 2005 documents.

The Panel noted that there was a discrepancy between the complaint and the response in this regard.

The supplementary information to Clause 15.4 of the 2003 Code referred in detail to calls on doctors stating that a representative should not normally call upon a doctor more than three times a year on average. This did not include attendance at group meetings, a visit requested by the doctor or a visit to follow up a report of an adverse reaction. The Panel noted that the representatives' personal performance grid did not refer to the requirements of Clause 15.4 of the Code but nonetheless considered that there was no evidence to show that representatives were encouraged to make six calls in six months as alleged. No breach of Clause 15.4 was ruled.

CONSIDERATION BY THE APPEAL BOARD

At the consideration of the report the Merck Sharp & Dohme representatives apologised on behalf of Merck Sharp & Dohme and stated that this matter was being taken extremely seriously by the company. The audit service was suspended in March 2006 in response to the complaint. The representatives submitted that this case had arisen as a result of a failure of its internal processes, including a breakdown in communication. The approval process had already been highlighted as a key priority for review following an internal review in October 2005 which was still ongoing. New standard operating procedures had been written and staff training had commenced. Internal disciplinary procedures were under way. The representatives submitted that the company was taking action to ensure that it never happened again.

The Appeal Board was extremely concerned that arrangements for the audit programme had highlighted very serious deficiencies in Merck Sharp & Dohme's procedures including the copy approval system. Given the significant investment that the audit represented the Appeal Board considered that it was inconceivable that it was not more tightly controlled; material had been used which had not been approved. The service had been clearly linked to the promotion of Cozaar and there appeared to be a serious lack of control by senior managers. The Appeal Board considered that the arrangements were totally unacceptable.

With regard to the Panel's ruling that the circumstances brought discredit upon the pharmaceutical industry, the Appeal Board was concerned that Merck Sharp & Dohme's actions had the potential to compromise patient safety by inappropriate prescribing. Further Merck Sharp & Dohme's actions would undermine both prescribers' and patients' confidence in the provision of properly conducted services. The Appeal Board was extremely concerned that some Merck Sharp & Dohme staff had not realised that the amended proformas and the slides used as training material were totally unacceptable in relation to the requirements of the Code.

The Appeal Board considered that this was an extremely serious case.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an immediate audit of Merck Sharp & Dohme's procedures. In addition Merck Sharp & Dohme would be publicly reprimanded and required to issue a corrective statement. The corrective statement should be sent as soon as possible to all practices that had been identified and approached to take part in the audit. In accordance with Paragraph 12.1 of the Constitution and Procedure the Appeal Board decided to report Merck Sharp & Dohme to the ABPI Board of Management with the recommendation that it suspended Merck Sharp & Dohme from membership of the ABPI.

CONSIDERATION OF THE AUDIT REPORT BY THE APPEAL BOARD

Upon receipt of the report of the audit carried out in July 2006 and Merck Sharp & Dohme's comments on

it, the Appeal Board noted that the company had started to implement the recommendations and address the observations set out in the audit report. This would take some time given that the problems were institutional in nature and many changes were necessary. This audit report would be provided to the ABPI Board.

The Appeal Board decided that Merck Sharp & Dohme should be reaudited. It was later decided that this audit would take place in November 2006 and the report of this audit would be made available to the ABPI Board.

CONSIDERATION BY THE ABPI BOARD OF MANAGEMENT

The ABPI Board noted that Merck Sharp & Dohme had been ruled in breach of Clauses 2, 9.1 and 18.1 of the Code. It also noted the audit report and Merck Sharp & Dohme's comments upon it.

The ABPI Board noted that the Appeal Board had recommended that Merck Sharp & Dohme be suspended from membership of the ABPI. It was further noted that Merck Sharp & Dohme was to undergo a second audit of its procedures in accordance with Paragraph 11.3 of the Constitution and Procedure; that Merck Sharp & Dohme was to be publicly reprimanded; and that Merck Sharp & Dohme had issued a corrective statement. The ABPI Board noted that Merck Sharp & Dohme had fully accepted responsibility for the matters giving rise to the complaint and that current management, including the new managing director, was taking action to ensure that there was no repeat: action which ranged from training through to changes in culture.

Nevertheless, given the serious nature of the case, the ABPI Board decided that the appropriate course of action was to suspend Merck Sharp & Dohme from membership of the ABPI for a minimum of three months commencing 2 October 2006. The suspension would be reassessed after three months. The ABPI Board noted that Merck Sharp & Dohme was to undergo a further audit of its procedures and requested that it be provided with a copy of the report for this second audit.

CORRECTIVE STATEMENT

In accordance with Paragraph 11.3 of the Constitution and Procedure, details of the proposed content of the corrective statement and the mode and timing of its dissemination were provided to the Appeal Board for approval prior to use.

The corrective statement was mailed in July 2006 to all surgeries which either participated in, or had been approached to participate in, the nurse audit programme.

'Dear Dr X

Following a complaint to the Prescription Medicines Code of Practice Authority (PMCPA), Merck Sharp & Dohme has been ruled in breach of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry in relation to an audit service, 'Hypertension review programme supportive of the GMS contract' offered to practices to assess patients with hypertension. The service was suspended in March 2006 and has now been stopped.

Internal documents, which had not been through the company approval system, were provided to the representatives and clearly linked the provision of the service to the use of Cozaar. The audit service was only to be offered to practices that agreed to use Cozaar as the medicine of choice in respect of nationally agreed guidelines. In some documents those guidelines had been altered in favour of Cozaar. The arrangements were considered to be completely unacceptable. Breaches of the Code (Clauses 2, 9.1 and 18.1) were ruled including a failure to maintain high standards and bringing discredit upon the pharmaceutical industry. I thus apologise unreservedly for the way in which Merck Sharp & Dohme conducted the audit.

In addition to the issue of this corrective statement, the Code of Practice Appeal Board decided that Merck Sharp & Dohme will be publicly reprimanded and undergo an audit of its procedures and policies for ensuring compliance with the Code. The matter is also the subject of a report to the ABPI Board of Management for it to consider whether further sanctions are necessary.

Should you have any further questions, please contact medical information at Merck Sharp & Dohme on 01992 45 5000.

As with all cases considered under the Code the case report giving full details will be published in due course (www.pmcpa.org.uk).

Yours sincerely

UK Managing Director
Merck Sharp & Dohme Limited'

Complaint received **15 March 2006**
Undertaking received **9 June 2006**
ABPI Board consideration **5 September 2006**