

# MEDIA/DIRECTOR v ROCHE

## Promotion of Tamiflu

An article published in The Financial Times 22 May 2010, entitled 'Roche accused of pressuring employee into illegal Tamiflu deals', reported matters raised during an employment tribunal, alleging that Roche pressurised its sales staff illegally to sell the prescription only medicine (POM) Tamiflu to people who were not doctors and incentivised customers with cash payments.

It was alleged that Roche had promoted Tamiflu to business continuity managers in companies keen to secure supplies of the scarce medicine for private stockpiles amidst growing concerns about a flu pandemic. The article referred to a special business unit, created in 2006 to sell Tamiflu to companies, being set unrealistically high commercial targets given the tight controls on the marketing of POMs. It was stated that there had been no efforts to ensure sales staff only spoke to health professionals and that Roche also sold Tamiflu to intermediary organisations employing medical staff, which in turn would sell the medicine to clients. It was reported that Roche had decided that it could speak about business continuity to non-medical customers provided that it did not mention the efficacy, dose or even the name of the medicine itself.

The article also reported that, to maintain market share, Roche had overcharged the NHS for its medicines by offering discounts from the official price to pharmacists and distributors. It was alleged that the company provided cash payments and discounts on future orders to customers so that they would buy its products rather than lower priced generics or parallel imports.

In accordance with the Authority's Constitution and Procedure the matter was taken up as a complaint by the Director.

The detailed response from Roche is given below.

The Panel noted the allegation that the company pressurised its staff to sell Tamiflu to people who were not doctors. The Code covered the promotion of medicines to members of the health professions and appropriate administrative staff. Thus POMs could be promoted to persons who were not doctors, such as senior NHS managers and the like, so long as the material or activity was relevant and tailored to the audience and otherwise complied with the Code. POMs could not be promoted to the general public.

The Panel noted Roche's submission that the members of the relevant business team would speak to a health professional or the person responsible for continuity planning. Tamiflu would

not be promoted to non-health professionals. Staff were given guidelines which stated 'If speaking to a doctor/nurse/medically qualified individual we discuss antivirals/Tamiflu. If speaking to non-medic, we talk generically about supporting their pandemic plan and that we would need to speak to their medical advisor to discuss medical support and POM's' [sic]. Tamiflu support materials could be given to those companies which did not have antivirals in their pandemic plan. The materials were to be supplied to 'medics only' and thereafter the conversation was terminated. For companies with antivirals in their pandemic plan, staff could discuss, *inter alia*, appropriate prescribing models and options and conclude with an order. It was difficult to see how a conversation with a 'non-medic' would fit with these guidelines. The Panel queried whether sufficient instruction in relation to companies without a medically qualified member of staff had been given.

The Panel was concerned that a sales aid which Roche stated in practice was only supplied to health professionals was certified for use with the business community and occupational health. The Panel also queried whether guidelines provided to staff were sufficiently clear about what materials were to be given to who. One document referred to sending a 'Letter/Brochure' to relevant persons 'Pharma – Medic, Others – Business Continuity Manager/General Manager.' This was followed by a list of approved materials but did not specify which were suitable for non-medically qualified people. The business continuity wallet, for example, might contain a sales aid if sent to a doctor. The Panel considered that the instructions to staff regarding the use of materials and about discussions with non-medically qualified persons were not sufficiently clear. Nonetheless taking all the circumstances into account there was no evidence to show that on the balance of probabilities Roche had actually promoted Tamiflu to a non-health professional as alleged. No breach of the Code was ruled.

The article referred *inter alia* to the provision of discounts and cash payments on future orders to customers. Roche noted that reference to discounts or cash equivalent rebates had been made in the tribunal proceedings but there was no reference to cash payments. Roche confirmed that it provided customers with rebates in the form of credit notes. The Panel noted that the supplementary information stated that measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 were outside the scope of the Code. Prices, margins and discounts were primarily financial terms. In

**principle credit notes and discounts which met the requirements of the relevant supplementary information were excluded from the Code. The Panel had no information about the nature of the credit notes provided by Roche. However there was no evidence before the Panel to indicate that inappropriate discounts or cash payments had been made contrary to the provisions of the Code thus no breach was ruled.**

An article published in The Financial Times 22 May 2010 was entitled 'Roche accused of pressuring employee into illegal Tamiflu deals'. The author reported matters raised during an employment tribunal case namely that Roche put pressure on its sales staff illegally to sell the prescription only medicine (POM) Tamiflu to people who were not doctors and incentivised customers by providing cash payments.

In accordance with Paragraph 6.1 of the Authority's Constitution and Procedure the matter was taken up with Roche as a complaint by the Director. The author of the article was asked whether he wished to be involved in the case or whether he had any additional information to submit. The author did not respond.

The matters at issue occurred during 2006 and thus the case was considered in relation to the requirements of the 2006 Code under the Constitution and Procedure of the 2008 edition of the Code.

## **COMPLAINT**

The article was about the pressurised selling of Tamiflu to people who were not doctors. It was alleged that Roche had promoted the medicine to business continuity managers in companies keen to secure supplies of the scarce medicine for private stockpiles when there were growing concerns about a flu pandemic.

The article specifically referred to a special business unit, created in 2006 to sell Tamiflu to companies, being set unrealistically high commercial targets given the tight controls on the marketing of POMs. It was stated that there had been no efforts to ensure sales staff spoke to health professionals and that Roche also sold Tamiflu to intermediary organisations employing medical staff, which in turn would sell the medicine to clients. Additional concerns were whether the discussions with companies over volumes of Tamiflu stock breached competition rules designed to ensure fair allocation of the scarce medicine and whether non-medical customers had the facilities to safely store and track their medicine. It was reported that the Medicines and Healthcare products Regulatory Agency (MHRA) had investigated a complaint from a business continuity manager who received a call from the Roche sales team but subsequently took no action.

It was reported that Roche had decided that it could speak about business continuity to non-medical

customers provided that it did not mention the efficacy, dose or even the name of the medicine itself.

Further it was alleged that Roche had overcharged the NHS for its medicines by offering discounts from the official price to pharmacists and distributors to maintain market share. It was alleged that the company provided cash payments and discounts on future orders to customers so that they would buy its products rather than lower priced generics or parallel imports.

When writing to Roche, the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1 and 18.1 of the 2006 Code.

## **RESPONSE**

Roche stated that the allegations were made in the context of an employment tribunal claim by an ex-employee who was aggrieved at being made redundant (the ex-employee claimed the real reason for his dismissal was because he made protected disclosures rather than a genuine redundancy). Although the tribunal hearing had concluded the decision had not been issued.

Roche stated that, with regard to the allegation about cash payments, the article in The Financial Times stated that Roche 'provided cash payments to customers' suggesting that cash was paid to individuals. The journalist had incorrectly reported the evidence. In his evidence to the tribunal, the ex-employee referred to Roche giving discounts or 'cash equivalent' rebates to customers. Roche confirmed that it had provided, and continued to provide, customers with rebates in the form of a credit note. This was standard commercial practice outside the scope of the Code. The ex-employee had not alleged that Roche had paid its customers cash. Indeed the ex-employee told the tribunal that he had never made any protected disclosure regarding inducements to prescribe.

In October 2006 the MHRA informed Roche that it had received a complaint to the effect that the commercial section of The Financial Times had received a telephone call from Roche suggesting that the company should consider purchasing antivirals for treatment and prophylaxis of its own staff (a copy of the letter was provided). There was no allegation that Roche had actually promoted Tamiflu or antivirals generally to the commercial team of The Financial Times. Roche had responded that, *inter alia*, it would only discuss Tamiflu with those people in an individual company involved in continuity planning and/or health professionals within an occupational health department should one exist (a copy of the response was provided). Roche had sought clarity on this statement from the author of the letter and his clear recollection was that this was not meant to imply that Tamiflu was promoted to non-health professionals. In its follow up (a copy of which was provided) the MHRA reminded Roche to ensure that discussions about a POM were limited to appropriate health

professionals. The author of Roche's response to the MHRA stated that although Tamiflu was not promoted to non-health professionals, he recalled reminding staff that they could only discuss Tamiflu with health professionals. Roche had not received any other complaints alleging inappropriate promotion of Tamiflu to private companies.

The ex-employee alleged that in 2006 Roche targeted business continuity managers in the promotion of Tamiflu. Neither The Financial Times article, nor the ex-employee, in his tribunal case, had produced any evidence to show that Roche had inappropriately promoted Tamiflu, and as stated above, the MHRA, at the time, did not rule that Roche had done anything wrong. The ex-employee's evidence to the tribunal was contradictory. On the one hand he alleged that Tamiflu was promoted to business continuity managers, and on the other he stated that he told his team that they could only discuss Tamiflu with a company's doctor. Despite being repeatedly challenged by the judge, the ex-employee was unable to provide any information to back up his claim that he had raised concerns with his managers about the promotion of Tamiflu to people who were not health professionals. Roche's investigation into this matter (including speaking to relevant employees) had failed to uncover evidence that Tamiflu was improperly promoted.

Roche explained that the ex-employee joined the company in 1995. In 2006 he was appointed to a new role reporting to the head of commercial. Roche had been unable to locate a job description but the primary responsibilities were to: manage the head office commercial development team; ensure professional delivery of commercial services within Roche inclusive of product and general commercial strategies through participation in the commercial development group management team; ensure the development of business for Tamiflu in the corporate sector.

This was not a business unit but rather a small team within the commercial department the main aim of which was to develop Tamiflu business within the private sector. Prior to this Roche had not sought to supply Tamiflu to the private sector. However, with the bird flu scare Roche started to receive a lot of requests for advice from companies about continuity planning in the event of a pandemic, including obtaining supplies of Tamiflu to protect their staff. Initially enquiries were handled by the customer services department with questions about Tamiflu being referred to medical information, but due to the increasing number of calls, and recognising the commercial opportunity, the specialist team under the ex-employee's leadership was established. Roche noted that at the time the government had encouraged companies to put in place plans to deal with a flu pandemic, and that antiviral therapy was seen as an important part of any such plan.

The ex-employee and his team would respond to requests from companies seeking supplies of

Tamiflu or advice around pandemic planning, or they would proactively contact companies. In the latter case they sought to speak to either the company's occupational health department or the person responsible for business continuity planning. The business aim was to get companies to develop pandemic plans and to consider antivirals as part of their plan. Guidance as to what the Roche team could say to customers was dealt with below.

Process flows relating to call structure and corporate prospecting were provided. These documents which were used by the specialist team as their primary reference tool contained the following guidance for staff: 'If speaking to a doctor/nurse/medically qualified individual we discuss antivirals/Tamiflu. If speaking to non-medical, we talk generically about supporting their pandemic plan and that we would need to speak to their medical advisor to discuss medical support and POMs'.

Roche submitted that the ex-employee's team would speak to either a health professional or the person responsible for continuity planning (which could be the same person). They would use the process flows mentioned above. The business continuity wallet and 'Survive' guidelines would be given to both health professionals and those who were not health professionals. Health professionals might also receive the drug information pack.

The main topic of discussion with non-medical staff was around business continuity plans. Roche staff asked if a company's plans for handling a flu pandemic included the supply of antivirals for employees. There was no evidence that Roche staff promoted Tamiflu in particular or antivirals in general to non-medical staff. If customers wanted to discuss Tamiflu they were told to do so through their occupational health department/medical adviser.

As a POM Tamiflu would only be supplied to organisations with one of the following: a wholesale dealer's licence; a registered pharmacy; a qualified doctor who would store the medicine under his/her own medical supervision (in this case Roche would check the doctor's General Medical Council number).

The journalist had incorrectly reported the evidence that was given to the employment tribunal. The ex-employee made no allegations about cash being paid to customers, and he specifically stated in evidence that he had not made any public interest disclosure relating to inducements to prescribe. He did, however, mention that Roche gave 'cash equivalent' rebates. Roche confirmed that it had provided, and continued to provide, rebates in the form of a credit note. This was standard commercial practice outside the scope of the Code.

Roche stated that the allegations reported in The Financial Times article were vague and not supported by any evidence. There were just the

bald assertions that Tamiflu was promoted to business continuity managers and that the company provided cash payments to customers. The ex-employee, in his evidence to the employment tribunal, made no allegations about cash payments, and he was unable to provide any specific details relating to improper promotion of Tamiflu. Roche had found no evidence that Tamiflu was promoted to non-medical staff. The MHRA in 2006 did not express any concerns about Roche's activities. Roche submitted that there was no breach of Clauses 2, 9.1 or 18.1 of the Code.

Roche subsequently provided a copy of the reserved judgement of the employment tribunal. Roche noted that the judgement did not mention cash payments to customers. Roche noted the parts of the judgement relevant to Tamiflu and a statement that 'on our findings of fact we are not satisfied that there was a disclosure of information which tended to show any failure in relation to the matters the claimant raised'.

In response to a request for further information from the Panel, Roche explained that the business continuity wallet would be provided to both health professionals and non-health professionals. This would be sent as a follow up to telephone contact that Roche made with a company, or would be left with a company representative responsible for continuity of planning following a meeting (that might be either a health professional or a non-health professional). The 'BC [business continuity] Wallet' and the 'Brochure' mentioned in the purple box at the bottom left of the Process for Corporate Prospecting were the same thing. If sent by post the wallet would be accompanied by a letter.

The wallet would have contained the 'Survive' guidelines. Health professionals would also have received as part of the pack a sales aid (referred to as 'marketing leavepiece' in the 'Process for 1:1 Call Structure').

The sales aid was certified as material for use with 'the Business Community and Occupational Health'. As the sales aid was a promotional item it should only have been certified for use with health professionals. However, according to one of the ex-employee's team who was still with Roche the certificate did not accurately reflect the intended audience, which was health professionals. The same individual had also confirmed that his recollection was that the sales aid was in practice only ever provided to health professionals. Thus whilst the audience stated in the certificate was not accurate (and this perhaps reflected the fact that it was created when Roche's Code knowledge and processes were not what they should have been), the sales aid was not in practice used inappropriately.

The e-mail address and freephone number referred to in both the wallet and the 'Survive' guidelines enabled continuity managers and health professionals to contact members of the specialist business team. The information provided would

depend upon the enquiry, but typically the enquiry would be dealt with in the same way as proactive contact by Roche with the enquirer (if a non-health professional or professional status unknown) being sent the wallet, 'Survive' guidelines and, for health professionals only, the sales aid and/or drug information pack.

Initial contact with companies was made by telephone. This would sometimes be followed up by a visit.

In conclusion, Roche noted that both in intent and practice, Tamiflu was not promoted to non-health professionals.

## PANEL RULING

The Panel noted that the published article which gave rise to this case referred to evidence submitted by an ex-employee of Roche to an employment tribunal. The tribunal had not published its decision when the article was published. Roche submitted that some points had been misrepresented.

The Panel noted the allegation that the company pressurised its staff to sell Tamiflu to people who were not doctors. The Code covered the promotion of medicines to members of the health professions and appropriate administrative staff (Clause 1.1). Thus POMs could be promoted to persons who were not doctors, such as senior NHS managers and the like, so long as the material or activity was relevant and tailored to the audience and otherwise complied with the Code. POMs could not be promoted to the general public (Clause 22.1).

The Panel noted Roche's submission that the members of the relevant business team would speak to a health professional or the person responsible for continuity planning. Tamiflu would not be promoted to non-health professionals. The 'Process for 1:1 Call Structure' flow chart featured a highlighted box at the top headed 'Guidelines' which stated 'If speaking to a doctor/nurse/medically qualified individual we discuss antivirals/Tamiflu. If speaking to non-medic, we talk generically about supporting their pandemic plan and that we would need to speak to their medical advisor to discuss medical support and POM's' [sic]. The flow chart referred to the provision of materials to support Tamiflu to those companies which did not have antivirals in their pandemic plan. The materials were to be supplied to 'medics only' and thereafter the conversation was terminated. For those companies which had antivirals in their pandemic plan the flow chart continued, discussing, *inter alia*, appropriate prescribing models and options and concluding with an order. It was difficult to see how a conversation with someone who was not medically qualified would fit with this flow chart. The Panel queried whether sufficient instruction in relation to companies without a medically qualified member of staff had been given. A separate flow chart 'Process for Corporate Prospecting' covered general enquiries about a company's position on pandemic

influenza planning. A highlighted box 'Guidelines' at the bottom of this flow chart again stated that 'If speaking to a doctor/nurse/medically qualified individual we discuss antivirals/Tamiflu. If speaking to non-medic, we talk generically about supporting their pandemic plan and that we would need to speak to their medical advisor to discuss medical support'.

The Panel noted Roche's submission about the material supplied to target groups. It was of concern that a sales aid which Roche stated in practice was only supplied to health professionals was certified for use with the business community and occupational health. The Panel also queried whether the flow chart 'Process for Corporate Prospecting' was sufficiently clear about what materials were to be given to who. It referred to sending a 'Letter/Brochure' to relevant persons 'Pharma – Medic, Others – [Business Continuity Manager]/General Manager.' This was followed by a list of approved materials but did not specify which were suitable for non-medically qualified people. The business continuity wallet for example might contain a sales aid if sent to a doctor. The approved letters were not further identified. The Panel noted Roche's submission in this regard. The Panel noted however that the covering letter for the drug information pack discussed Tamiflu in the prevention of influenza. The Panel considered that the instructions in the flow chart 'Process for Corporate Prospecting' regarding the materials' intended audience and in the flow chart 'Process for 1.1 Call Structure' about discussions with non-medically qualified persons were not sufficiently clear. Nonetheless taking all the circumstances into account there was no evidence to show that on the balance of probabilities Roche had actually

promoted Tamiflu to a non-health professional as alleged. No breaches of Clauses 9.1 and 2 were ruled.

The article referred, *inter alia*, to the provision of discounts and cash payments on future orders to customers. Roche noted that reference to discounts or cash equivalent rebates had been made in the tribunal proceedings but there was no reference to cash payments. Roche confirmed that it provided customers with rebates in the form of credit notes. The Panel noted that the supplementary information to Clause 18.1 stated that the measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 were outside the scope of the Code and were excluded from the provision of Clause 18.1 which related *inter alia* to gifts and inducements. Prices, margins and discounts were primarily financial terms. In principle credit notes and discounts which met the requirements of the relevant supplementary information were excluded from the provisions of Clause 18.1. The Panel had no information about the nature of the credit notes provided by Roche. However there was no evidence before the Panel to indicate that inappropriate discounts or cash payments had been made contrary to the provisions of Clause 18.1. Thus no breach of that clause was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2 on this point.

<b>Complaint received</b>	<b>25 May 2010</b>
<b>Case completed</b>	<b>5 July 2010</b>

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