

## EX-EMPLOYEE and MEDIA/DIRECTOR v ROCHE

### Supply of Xenical and support for a slimming clinic

In Case AUTH/2099/2/08, a former Roche employee complained about the supply of Xenical (orlistat) to a bogus health professional and the funding of a clinic by Roche.

The Panel noted that the complainant had referred to an article in the Financial Times which alleged that Roche had sold large quantities of Xenical to the operator of a chain of private UK diet clinics, in spite of suspicion at one stage that the product was being sold illegally, and agreed to provide him with £55,000 for the purchase of another diet clinic. In accordance with established practice the matter was taken up as a complaint under the Code (Case AUTH/2100/2/08).

In Case AUTH/2099/2/08, with regard to the supply of Xenical, the Panel was extremely concerned about the circumstances which had led to a prescription only medicine in effect being supplied to a person who was not a health professional and by that person to patients. The Panel noted Roche's submission that it had validated the General Medical Council (GMC) number of the doctor named on the new account proposal form. The Panel considered that companies needed to be particularly careful about the supply of medicines to private clinics. It noted that Roche had made enquiries about the doctor but not about the owner who claimed he was a pharmacist, but was not. The FT article referred to a report written by a member of Roche's staff posing as a new client in May 2003 which described how [the owner] '... personally sold him Xenical ...' and that 'To a lay person he would have passed as a doctor'. The Panel considered that Roche had not paid sufficient attention to ensuring that the supply of its product to the private clinic was appropriate. Thus the Panel ruled a breach of the Code. The Panel considered that the arrangements brought discredit upon the pharmaceutical industry and a breach of Clause 2 of the Code was ruled. Upon appeal by Roche, the Appeal Board noted that the company should have strongly suspected that the manner in which Xenical was prescribed at the clinic was inappropriate and possibly prejudicial to patient safety. The Panel's rulings were upheld.

The Panel noted that Roche had agreed to sponsor the purchase of another diet clinic. Payment was to be in two parts, £20,000 payable in August 2004 and £35,000 in January 2005. According to Roche only £20,000 had been paid. The second payment had been halted following contact by the Medicines and Healthcare products Regulatory Agency (MHRA).

Roche had agreed to pay the money in August

2004. This meant that the applicable Code was the 2003 Code.

The supplementary information to the 2003 Code stated that medical and educational goods and services could be provided if they enhanced patient care or benefited the NHS. The provision of such goods and services must not be done in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine.

It was difficult to see how providing £55,000 to an individual to purchase a private diet clinic was a medical and educational good or service that would enhance patient care or benefit the NHS as required by the Code. Thus the Panel ruled a breach of the 2003 Code. The Panel did not consider that Roche had maintained high standards in relation to its agreement to provide an individual with £55,000. A breach of the Code was ruled. The Panel considered that the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

In Case AUTH/2100/2/08, with regard to the supply of Xenical, the Panel was extremely concerned about the circumstances which had led to a prescription only medicine in effect being supplied to a person who was not a health professional and by that person to patients. The Panel noted Roche's submission that it had validated the GMC number of the doctor named on the new account proposal form.

The Panel noted that the contract did not stipulate that the professional status of the signatory be included. Roche had not confirmed the professional status of the clinic owner whom it submitted had posed as a pharmacist. The Panel considered that in effect Roche had sold a prescription only medicine to a member of the public. The Panel was extremely concerned about the arrangements, particularly given that someone from Roche had visited the diet clinic in May 2003 and had been seen by the owner. The report of that visit noted that to the lay person the owner would have passed as a doctor as he 'had the bag and sphygmomanometer etc to almost prove it'. The document used the term 'prescribed' and reported that the owner was clearly not a fan of Xenical. The Panel considered that companies needed to be particularly careful about the supply of medicines to private clinics. It noted that Roche had made enquiries about the doctor but not about the owner who claimed to be a pharmacist. The clinic visit report in May 2003 from the Roche employee should have led to further action on Roche's part and the company to question supply

of Xenical to the clinic in 2004. The Panel considered that Roche had not paid sufficient attention to ensuring that the supply of its product to the private clinic in question was appropriate. Thus the Panel ruled a breach of the Code. The Panel considered that the arrangements brought discredit upon the pharmaceutical industry and a breach of Clause 2 of the Code was ruled. Upon appeal by Roche the Appeal Board noted that the company should have strongly suspected that the manner in which Xenical was prescribed at the clinic was inappropriate and possibly prejudicial to patient safety. The Panel's rulings were upheld.

The Panel noted that Roche had agreed to sponsor the purchase of a further clinic. Payment was to be in two parts, £20,000 payable in August 2004 and £35,000 in January 2005. According to Roche only £20,000 had been paid. The second payment had been halted following contact by the MHRA. A document prepared by a Roche employee headed 'Private Clinic Funding Proposal' was undated. It stated that if Roche agreed to the proposal it was hoped to complete purchase of the diet clinic before the end of June 2003. The Private Clinic Funding Proposal also included sales analysis data for 2003 and 2004 showing the return on a £55,000 investment. The Private Clinic Funding Proposal referred to the diet clinics as 'a real Xenical success story'. The owner was reported as having put enormous efforts into establishing Xenical across his group of clinics as the medicine of choice for safe and effective long-term weight loss.

The Panel considered that the proposed payment of £55,000 for the clinic was linked to the use of Xenical. The proposal had been made on the basis that Xenical would become the medicine of choice at the clinic. The Private Clinic Funding Proposal stated that the current treatment guideline at the clinic was not to use Xenical. The proposal produced by the Roche employee focussed only on the increased use of Xenical. There was nothing in the proposal to suggest that Roche had considered whether or not this was a medical or educational good or service. There was no evidence to show that Roche considered the proposal in relation to anything other than the potential increased use of Xenical. It was difficult to see how providing £55,000 to an individual to purchase a private diet clinic was a medical and educational good or service that would enhance patient care or benefit the NHS as required by the Code. Thus the Panel ruled a breach of the Code.

The Panel did not consider that Roche had maintained high standards in relation to its agreement to provide an individual with £55,000. A breach of the Code was ruled. The Panel considered that the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel also considered that in both cases the circumstances warranted consideration by the

Appeal Board in relation to the possibility of additional sanctions. Thus the Panel reported Roche to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board noted that the report from the Panel concerned both the supply of Xenical and the funding of the clinic. The Appeal Board was extremely concerned about these cases, particularly with reference to Roche's disregard for patient care. The payment for the purchase of the clinic was clearly linked to the prescribing of Xenical and thus totally unacceptable. The Appeal Board decided that Roche would be publicly reprimanded and reported to the ABPI Board of Management with the recommendation that the company be suspended from membership of the ABPI.

The ABPI Board noted that Roche had been ruled in breach of the Code including Clause 2. It also noted that Roche had been audited three times and a fourth audit was arranged for September in relation to another unrelated case.

The ABPI Board noted Roche's submission that the MHRA had not suggested any wrong-doing by Roche. However, it believed that funding of the clinic, and Roche not taking any action in relation to the supply of Xenical to the clinic following the visit by the Roche employee posing as a new patient in 2003, were very serious matters.

The ABPI Board agreed that Roche would be suspended from membership of the ABPI for a period of six months commencing 14 July 2008 with re-entry conditional upon the audit which the company was to undergo in September proving satisfactory to the Board.

#### CASE AUTH/2099/2/08

A former employee of Roche Products Limited complained about the supply of Xenical (orlistat) to a bogus health professional and the funding of a clinic by Roche.

#### **COMPLAINT**

The complainant stated that in early 2005, two senior colleagues told her that Roche had been involved with funding and supplying medicines to a bogus doctor who had been providing slimming medicines – including Xenical – to patients at a 'clinic' held on the site of a 'tanning and toning' beauty parlour. They told the complainant this because they had received a telephone call from the Medicines and Healthcare products Regulatory Agency (MHRA) notifying them of a visit by an MHRA enforcement officer in relation to this bogus doctor. The MHRA had been informed about the bogus doctor because one of the patients who attended the 'clinic' had suffered an epileptic fit. The neurologist who treated the patient subsequently reported the incident to the MHRA.

The complainant telephoned her manager in Switzerland later the same day, and told him what she had learned. Eight working days later, her employment was terminated and she was escorted from the Welwyn premises.

Given the circumstances of her dismissal, the complainant lodged a claim of unfair dismissal with the Employment Tribunal Service. At the end of the hearing the complainant was awarded unfair dismissal and reinstatement (which Roche refused to comply with).

The complainant alleged that throughout the tribunal hearing, various intimidating tactics were used by Roche. In the first instance it claimed that the reason for the complainant's dismissal was gross professional misconduct, an accusation that it withdrew on day one of the hearing and changed to 'some other substantial reason'. In addition, Roche brought in witnesses including an enforcement officer from the MHRA who the complainant had previously met at the MHRA to inform him and his colleagues of Roche's activities regarding the funding of the bogus doctor and the slimming clinic.

The complainant also alleged that Roche also gave a statement to the BMJ that portrayed the complainant as 'a concerted troublemaker, addicted to rowing with senior colleagues and unable to obey orders from above'. The complainant submitted that evidence produced at the tribunal hearing could substantiate none of this, and previous appraisals and employment references described the exact opposite.

In the meantime, the complainant had been informed by an unofficial but reliable source, that whilst the bogus doctor had been charged, tried (entering a guilty plea) and was about to be sentenced, no action had been taken against Roche which in her opinion had knowingly aided and abetted him.

In its defence, Roche claimed that it thought the bogus doctor was a pharmacist – which he was not – and so considered that it 'did nothing wrong' in supplying him with Xenical and observing him at first hand supplying this medicine to patients. The complainant was completely astounded by this and had letters from the Department of Health (DoH) confirming that no legal action was to be taken against Roche. The complainant therefore lodged a complaint against Roche for contravening the Code regarding the supply of Xenical to a bogus doctor and the funding of the slimming clinic.

The complainant provided a copy of an article from The Financial Times (FT) 12 February written by Andrew Jack [This became the subject of Case AUTH/2100/2/08]. The complainant stated that the FT article detailed Roche's activities with Xenical. The complainant offered to provide more information and details. When asked by the Authority to supply any material in writing to be considered none was provided.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 9.1, 17 and 18 of the Code.

## RESPONSE

Roche stated that the background to this complaint was complex and spanned the last five years.

- Roche and other pharmaceutical manufacturers were the victims of criminal activity relating to a group of private diet clinics.
- From March 2005 Roche supported the MHRA at all levels to provide information and intelligence for it to build a criminal case against two individuals. One had posed as a pharmacist and treated patients for obesity, including the provision of prescription medicines.
- It later transpired that the latter was employed by another pharmaceutical company as a medical sales representative and the other was his previous line manager selling their company's anti-obesity treatment.
- The case was heard in court (November 2007) and both defendants pleaded guilty (one to five offences and the other to one offence against the Medicines Act) and awaited sentencing.
- Over the course of its investigation the MHRA had seen all related Roche internal documents and had cleared Roche of any wrong-doing in relation to this complex case. In fact the MHRA had thanked Roche for its co-operation and support to help it prosecute these individuals.
- Similarly, Roche had been engaged in an employment tribunal with the complainant for the last 3 years who claimed her dismissal from the company was a result of whistle blowing when questions about the diet clinic came to light – something which Roche strongly refuted. The employment tribunal found that as Roche did not follow the correct dismissal process the complainant was unfairly dismissed. Roche acknowledged the unfair dismissal, however this was not for whistle blowing. The claimant's whistle blowing claim was therefore not upheld. The employment tribunal was still ongoing as the claimant had appealed this ruling.
- The claimant had similarly approached the MHRA during the course of her tribunal claim, the MHRA did not take any action against Roche as a result of that approach, as the claimant did not raise any new issues.
- Thus this was a very complex situation of which detailed information had already been heard by a criminal court of law, an employment tribunal, and full documentation had been reviewed by the MHRA.

Roche would not respond to matters that related to the complainant's dismissal or the employment tribunal. Roche therefore responded to the complainant's specific comment around raising a formal complaint for 'contravening the Code regarding the supply of Xenical to a bogus doctor and the funding of a Slimming Clinic', which Roche

discussed in relation to Clauses 2, 9.1, 17 and 18.

Roche explained that from 2002 it took the first step into a new market place – that of private slimming clinics. Roche was in contact with a private slimming clinic which it understood was owned by a pharmacist who was supported by a doctor. Roche had met the doctor and the owner on a regular basis, though the latter clearly drove the initiative.

The clinic requested Roche supplied it directly with Xenical and in line with standard procedure, Roche validated the General Medical Council (GMC) number of the doctor. Roche was able to confirm the legitimacy of the doctor and it therefore authorised direct distribution of stock. This was the standard procedure for such an arrangement and all information and facts in relation to the clinic appeared to be accurate. There was a health professional qualified to prescribe Xenical working at the clinic, which was verified and clearly the doctor was legitimate and therefore Roche submitted that a breach of Clause 17 was not justified.

Roche assumed that the complainant was referring to discussions Roche had with the owner in relation to a slimming clinic located elsewhere and Roche responded on that basis.

As part of Roche's ongoing discussions with the first clinic, the owner positioned himself as owning several other clinics in the UK, and that he proposed to set up another clinic which was otherwise about to close. He approached Roche in 2004 for funds to support the setup costs. Before it made any such decision Roche analysed internally whether such an investment would be in its longer term interests, and in this instance it concluded that it would. In addition it would benefit the local patients who had used the clinic and others who would do so in future. Roche therefore agreed to sponsor the clinic for £55,000 with two payments spread over six months, as evidenced by confirmation from the owner of the first clinic and the invoice. This funding was not linked to the clinic's prescribing of Xenical. The funding was part paid - Roche paid the first instalment of £20,000 but the final payment of £35,000 was stopped when it was contacted by the MHRA and suspicions were raised about the owner's legitimacy.

In March 2005 the Enforcement Division of the MHRA advised Roche that it was investigating allegations of criminal activity at a diet clinic supplied by Roche and other pharmaceutical companies. The MHRA asked Roche to continue supplying the clinics with Xenical whilst its investigation was ongoing and it co-operated fully with the request and with the investigation. Roche believed that in working with the MHRA it had maintained the high standards of the industry and it refuted a breach of Clause 9.1.

Roche was a victim of criminal activity in this case and had worked with the MHRA to ensure that there

was sufficient evidence to convict the individual involved. Roche argued that as such it had maintained high standards (Clause 9.1).

Roche noted that it had withdrawn from the private slimming market, and had stopped direct supply of Xenical to any diet clinic.

Funding of the further clinic would fall under Clause 18 Medical and Educational Goods and Services in the 2003 Code. Roche was approached by the owner of the original clinic to provide sponsorship and, recognising the benefit to patients in the proposed new location, agreed. As such, Roche refuted that this was a breach of Clause 18, as the sponsorship was not linked to the prescribing of its product.

As victims of criminal activity, Roche did not consider its actions discredited the industry (Clause 2) and that high standards had been maintained (Clause 9.1). Roche had worked with the MHRA to assist it with its actions in relation to the criminal behaviour and the MHRA which had investigated Roche for any improper behaviour had no further concerns.

## **PANEL RULING**

The Panel noted Roche's submission that the MHRA had seen all related Roche internal documents and had cleared the company of any wrong-doing. The Panel noted Roche's submission that it was a victim of criminal activity. The Panel's role was to consider the matter in relation to the Code which was not the role of the MHRA.

The Panel noted that the activities had taken place in 2003 and 2004. The applicable Codes would be the 2001 Code and the 2003 Code. With regard to Clause 2, there was no difference between the requirements in the 2001 and 2003 Codes. Clause 9.1 in both the 2001 Code and 2003 Codes required that high standards be maintained. Other wording in Clause 9.1 of the 2001 Code had become Clause 9.2 in the 2003 Code. Taking all these factors into account, the Panel decided it would make its rulings in relation to the 2003 Code using the Constitution and Procedure in the 2006 Code.

The Panel was concerned that Roche had supplied less information in relation to this case than it had in Case AUTH/2100/2/08 which concerned the article published in the FT, 12 February 2008.

The Panel noted that Roche had been asked to respond in relation to a number of clauses of the Code, including Clause 17. On reviewing Roche's response the Panel did not consider that Clause 17 of the 2003 Code was relevant to the activities in question and thus that clause was not considered. The complainant's allegations related to the supply of Xenical to a bogus doctor and the funding of a clinic.



The Panel noted that the complainant had referred to the article in the FT. The article alleged that Roche had sold large quantities of Xenical to the operator of a chain of private UK diet clinics in spite of suspicion at one stage that the product was being sold on the 'grey market'. Roche had agreed to provide £55,000 for the purchase of another diet clinic.

With regard to the supply of Xenical, the Panel was extremely concerned about the circumstances which had led to a prescription only medicine in effect being supplied to a person who was not a health professional and by that person to patients. The Panel noted Roche's submission that it had validated the GMC number of the doctor named on the new account proposal form. The Panel considered that companies needed to be particularly careful about the supply of medicines to private clinics. It noted that Roche had made enquiries about the doctor but not about the owner who claimed he was a pharmacist. The FT article referred to a report written by a member of Roche's staff posing as a new client in May 2003 which described how the latter '... personally sold him Xenical ...' and that 'To a lay person he would have passed as a doctor'. The Panel considered that Roche had not paid sufficient attention to ensuring that the supply of its product to the private clinic was appropriate. Thus the Panel ruled a breach of Clause 9.1. The Panel considered that the arrangements brought discredit upon the pharmaceutical industry and a breach of Clause 2 was ruled.

The Panel noted that Roche had agreed to sponsor the further clinic. According to documents (on clinic headed paper) from the owner payment was to be in two parts, £20,000 payable in August 2004 and £35,000 in January 2005. According to Roche only £20,000 had been paid. The second payment had been halted following contact by the MHRA.

The Panel noted that Roche had agreed to pay the money in August 2004. This meant that the applicable Code was the 2003 Code.

The supplementary information to Clause 18.1 of the 2003 Code stated that medical and educational goods and services could be provided if they enhanced patient care or benefited the NHS. The provision of such goods and services must not be done in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine.

It was difficult to see how providing £55,000 to an individual to purchase a private diet clinic was a medical and educational good or service that would enhance patient care or benefit the NHS as required by the Code. Thus the Panel ruled a breach of Clause 18.1 of the 2003 Code. The Panel did not consider that Roche had maintained high standards in relation to its agreement to provide an individual with £55,000. A breach of Clause 9.1 was also ruled. The Panel considered that the arrangements

brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel also considered that the circumstances warranted consideration by the Code of Practice Appeal Board in relation to the possibility of additional sanctions. Thus the Panel decided to report Roche to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

## **APPEAL BY ROCHE**

Roche noted that Clause 1 of the 2006 Code, set out the scope of the Code. Clause 1.2 stated that 'The term "promotion" means any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines'. Roche submitted that the commercial supply of medicine was not a promotional activity and therefore it did not fall under the scope of the Code. Commercial supply fell under the scope of the MHRA and specifically under the scope of the 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors' - the orange guide.

Although Roche considered the commercial supply of medicines fell outside the scope of the Code it demonstrated the robust processes and checks it carried out prior to supply of Xenical to the original clinic.

Roche noted that the Panel was extremely concerned about the circumstances which had led to a prescription only medicine in effect being supplied to a person who was not a health professional and by that person to patients. Roche as a wholesale dealer complied with UK legislation on wholesale distribution as stated in 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors' compiled by the Inspection and Standards Division of the MHRA, Chapter 9, Section 9.

Within the UK Roche supplied to other wholesale dealers who held valid licences as issued by the MHRA, hospital pharmacies, having checked their validity in the hospital yearbook, retail pharmacies where they were registered with the Royal Pharmaceutical Society of Great Britain (RPSGB), and clinics and dispensing doctors, under the supervision of a GP, having checked their status with the General Medical Council via their GMC certificate.

Roche submitted that it had presented its own internal 'Guidelines for Opening New Accounts and Bona fide checks' to an MHRA inspector at an importation audit carried out in January 2007. This was a standard audit by the MHRA and was not related to the diet clinics or any other event. The auditor's only recommendation was that Roche create a GMP relevant Standard Operating

Procedure and this was actioned and last reviewed on 2 April 2007.

When selling prescription only medicines Roche and other pharmaceutical companies sold to the organisation, not an individual, and ensured that either the organisation had an approved licence to supply prescription only medicines or alternatively had a responsible person attached to that organisation who could lawfully administer the prescription only medicines.

- For wholesalers Roche sold directly to a wholesaler branch which was under the supervision of the Responsible Person. In practice the owner of the wholesaler was not the Responsible Person and the ordering was generally carried out by a buyer or replenishment coordinator.
- Roche sold directly to retail pharmacists and it would check that they were registered with the RPSGB, however the ordering from that retail pharmacist could be performed by a locum, or general pharmacy staff rather than the registered pharmacist who took ultimate responsibility for product ordering, storage and dispensing. The pharmacy owner was not necessarily the registered pharmacist or Responsible Person but they had a duty to nominate a Registered Pharmacist as their superintendent.
- In supplying GPs or dispensing doctors, Roche sold to the organisation, not the individual. Roche ensured that there was a GP with a valid GMC certificate at the delivery address to take full liability for the procurement, storage and dispensing of product. This approach was in line with other wholesaler dealers and complied with current legislation, and was the approach taken in supply of Xenical to the diet clinic.

Therefore Roche submitted that it was in line with standard practice of other wholesaler dealers, and it had fully adhered to the legal requirements as set out by the MHRA in supply of medicine and validated by the MHRA audit, previously discussed, in January 2007. The fact one of the parties provided a prescription only medicine to patients was his responsibility and that was why he was successfully prosecuted by the MHRA, which Roche had fully supported from the outset.

Roche considered that if the Appeal Board upheld the Panel's rulings of breaches of Clauses 2 and 9.1 in Cases AUTH/2099/2/08 and AUTH/2100/2/08, there would be significant implications on how current UK legislation for wholesaler distribution was interpreted and applied, and on how the entire pharmaceutical industry and wholesalers conducted business.

Roche disagreed with the Panel's view that the company had not paid sufficient attention to ensuring that the supply of its products to the private clinic was appropriate.

With specific regard to the group of slimming

centres Roche sold Xenical to one slimming clinic and carried out the following detailed review to check the validity of the centre:

- A Roche medical representative visited the slimming centre to meet the lead doctor and business owner and to see the clinic and how it operated. A report was produced detailing:
  - The centre's addresses and telephone numbers
  - Treatment protocol and guidelines
  - Doctors' names at each location
  - Opening times for each centre
- When the account opening form was completed and returned to Roche it established that the doctor who met the medical representative at the field visit had provided his GMC number and this went through the Roche standard procedure for opening new accounts with the doctor's name and number being checked through the GMC website. In addition other checks were completed such as the financial security of the organisation.
- Advertisements in local newspapers showed that the slimming centres were active in the local market.
- The clinic also advertised within the local GP surgery appointment cards highlighting links with general practice.
- Once the account was opened the medical representative visited the account and met the doctor and business owner.
- Roche monitored the sales of Xenical in total and by individual purchaser. At the peak of its sales to the entire private sector the quantity of Xenical sold to all private clinics was 5.5%.
- Once Roche realised that the quantity being purchased through the group of clinics was higher than expected for the private sector then a member of the market analyst team visited the centre and other larger buying centres to validate their models and patient numbers. In addition to this the analyst also measured sales in the surrounding areas to see whether Roche were experiencing a corresponding fall in volume to standard wholesalers. This was to provide additional assurance with regard to supply of Xenical.
- Roche limited the amount of stock that the diet centre could order, whilst its investigation was underway. The cap on the sales quantity was still in place when the MHRA enforcement team visited.

Roche also sent a member of staff to the clinic to act as a new patient in order to provide additional assurance that the Xenical supplied to the group was being dispensed and the group was not acting as a wholesaler and supplying the packs to other chemists/wholesalers.

In this regard Roche submitted that a significant amount of time was taken in investigating the sales to the clinic to ensure the validity of the sales through this group. In addition as far as Roche was

aware at least one other pharmaceutical company had seen that this group was legitimate and had also supplied a prescription only medicine.

In summary, Roche submitted that the commercial supply of medicines did not constitute promotion as defined in Clause 1.2 and therefore considered its commercial supply of Xenical to the diet clinic to be outside of the Code. If the Appeal Board took the view that the Code did apply then Roche challenged the findings that it was in breach of Clauses 9.1 and 2. Roche had done all that a responsible pharmaceutical company would and should have done in the circumstances and strictly followed legislative process. Roche noted that pharmaceutical companies supplied an organisation, not an individual and the clinic had a doctor qualified to prescribe Xenical. The fact the owner of the clinic was not qualified was not relevant for this purpose, although Roche genuinely believed at the time that he was a pharmacist. If the clinic had not had a doctor Roche would not have supplied to it.

### COMMENTS FROM THE COMPLAINANT

The complainant noted that Roche disagreed that insufficient attention was paid to the supply of its products to the private clinic. The complete process undertaken by Roche when the account opening form was completed and returned was to establish that the doctor whom the medical representative met at the field visit had provided his GMC number. This went through the Roche standard procedure for opening new accounts with the doctor's name and number being checked through the GMC website. The complainant alleged that within the Employment Tribunal evidence was a string of emails dated from 26 April 2000, whereby a Roche employee stated that he believed that the supply of Xenical to the slimming clinics contravened EU Directive 65/65 and the 1968 Medicines Act; he was concerned that Roche was supplying to the clinic and not directly to the doctor. He stated that it was irrelevant that a doctor prescribed/dispensed – the law in question was about supply and that Roche had to legally supply to an authorized body. He emphasized that the onus of the law was clearly on the supplier (Roche) as there was no guarantee that a product would be legally dispensed if it were supplied to an unlicensed body. He clearly told his Roche commercial and legal colleagues that unless the clinics were licensed in some way, Roche was outside the law. Indeed invoices from Roche, which were also supplied to the Employment Tribunal, showed that from 28 March 2002 until 20 January 2005 Xenical shipments all went to a clinic which was not the address of the 'clinic' that the doctor apparently supervised and which appeared on the New Customer Form supplied by Roche in its appeal.

The complainant alleged that also contained in the Employment Tribunal evidence, was an email concerning supply of Xenical to slimming clinics,

dated around the time of the announcement of the MHRA Enforcement visit on 4 March 2005. In it the correspondent described his concerns that, as the Responsible Person named on Roche's GDP licence, he was personally accountable if *bona fide* checks of purchasers had not been performed properly. He reminded the recipient of the email he sent him in April 2000 and he repeated that, in his opinion, Roche had not performed sufficient verification checks with respect to the slimming clinics. Although Roche believed the owner was a pharmacist, it had not checked his registration with the RPSGB.

The complainant noted that in response to an item on BBC Radio 4 Today Programme, 4 April 2008 Roche issued two statements to the BBC describing the verification checks that it had done before supplying Xenical to the slimming clinic. In short, Roche changed its story when probed by the BBC journalist. It was therefore difficult to see how Roche's comments regarding its checking of the validity of the centre could be upheld. The complainant strongly suggested that the Appeal Board requested the evidence from Roche that it provided to the Employment Tribunal.

The complainant noted that Roche had stated that it had monitored the sales of Xenical in total and by individual purchaser. At the peak of its sales to the entire private sector the quantity of Xenical sold to all private clinics was 5.5%. Once Roche realized that the quantity purchased through the clinics was higher than expected for the private sector a member of the company's market analyst team visited the centre and other large buying centres to validate their models and patient numbers. In addition to this the analyst also measured sales in the surrounding areas to see whether Roche had experienced a corresponding fall in volume to standard wholesalers. This was done in order to provide additional assurance with regard to supply of Xenical. Roche limited the amount of stock that the diet centre could order, whilst its investigation was underway. The cap on sales quantity was still in place when the MHRA Enforcement team visited.

The Roche commercial person who visited the owner reported to Roche in December 2003 that: 'As yet we have invested almost no money in any of these clinics and we are gaining sales despite this. I am sure that with some often low level investment we can develop many of these models and drive even greater Xenical sales'. He described in detail the fact that the owner wanted to buy out another private clinic which had 16,000 patients on its books of which 5000 were said to be active. From the rough calculations that the owner had carried out he expected that business could almost double. The investment in the clinic would be about £55,000 of which the owner wanted a significant contribution from Roche. The Roche employee reported that the clinic he visited was part of a 'tanning and toning salon', however he did not witness any patients in attendance when he visited. Whilst visiting the owner, he also reviewed confidential patient records

and based on this review he stated that his initial scepticism about the clinic had been drastically reduced and that he was convinced that a large number of patients were going through the clinic. He advised against closing down trading terms with the clinic and stated that the only worst-case scenario would be if they stopped buying Xenical. He stated that: 'I feel that we may be sacrificing sales just because we are scared of the potential of the private sector'. Roche's primary concern was that Xenical shipped to the owner was entering the grey market and it was concerned that the large quantities of Xenical that it shipped to the slimming clinic were being sold on at a profit. He fully supported the investment in the new clinic and advocated the payment be made in two lump sums, '...On the question of funding the expansion in the slimming clinic in ....., it is hard to see an argument against based on the fact that I am almost entirely convinced of the validity of the current business model. The £55k request would be recouped within a few months. 500 packs per month = £15k per month and the full amount would be returned within 4 months. I would possibly recommend a more conservative approach of half this on completion of the purchase and the remainder after a few months of Xenical purchase to remove some of the risk. This depends on the requirement of the funding for the initial purchase'. Based on this evidence, it is difficult to see how Roche could have agreed to the payment of £55,000 to the owner as an 'unrestricted grant' which was what Roche claimed in response to the Today programme and the FT article. The complainant understood that the intent behind allowing pharmaceutical companies to make unrestricted grants was that they were given to a third party for the purpose of research or education and not for the financial benefit of the donor.

Indeed, in its response Roche stated that it had analysed the owner's approach for funds to see if such an investment would be in the company's longer term interest and that it concluded that it would.

The complainant alleged that it was clear that Roche's investment in the new slimming clinic was purely motivated by its desire to increase the sales of Xenical. The complainant questioned whether Roche could provide documentary evidence that it had limited the amount of Xenical that the clinic could order.

The complainant noted that Roche had also sent a member of staff to the existing clinic to act as a new patient, in order to provide additional assurance that Xenical being supplied to the group was being dispensed and the group was not acting as a wholesaler and supplying packs to other chemists/wholesalers

The person Roche sent to the owner's clinic to act as a patient seeking help with weight loss described in his report how, in May 2003, he attended the clinic which advertised itself as offering health, beauty,

skin, nail and massage for men and women. He described the clinic as a former corner shop, with the front room as a reception area and the rear rooms and upstairs having been converted as a beauty clinic. He was seen by the owner. In his report he stated: 'To a lay person he would have passed as a doctor and had the bag, sphygmomanometer etc to almost prove it'. The complainant noted that Roche already knew at this point that he was not a doctor as they believed him to be a pharmacist. The 'patient' had his 'history' taken briefly by the owner and it rapidly became clear that he was going to be prescribed one of three medicines. He asked for Xenical and was given a Welwyn pack of Xenical in exchange for £75.

The complainant alleged that based on this evidence, it was clear that Roche knew that the owner was supplying Xenical without a valid doctor's prescription in May 2003 and yet it continued to supply him with Xenical. Indeed, the invoices for supplies of Xenical to the clinic were dated up to March 2005. In short, following the mystery patient visit, instead of notifying the MHRA and police of his activities, Roche continued to supply him for nearly two years until the MHRA Enforcement visited the Roche Welwyn site in March 2005. Easily-conducted checks with the RPSGB register would have verified if the owner was a pharmacist.

The complainant noted that Roche had stated that over the course of the MHRA investigation the MHRA had seen all related Roche internal documents. Roche had called part of its submission to the Employment Tribunal the 'MHRA Bundle'. However, its table of contents indicated that not all of its contents had been supplied to the MHRA. Documents not disclosed at the time included the transcript of a conversation involving the owner's wife in February 2005. This transcript stated that his wife knew that Roche was giving £55,000 to the owner to set up another clinic. She also stated that he was buying Xenical from Roche at levels of between £79,000 and £89,000 per month. In this transcript, she also stated that a patient who had been given a product by her husband suffered an epileptic fit.

The complainant noted that Roche had stated that as it had confirmed the legitimacy of the doctor it had therefore authorized direct distribution of stock. The complainant alleged that the Xenical sales were made to another clinic. Therefore this did not constitute 'direct distribution of stock' to the location where Roche considered the doctor to be based. The address of the other was the address on a wholesale dealer's licence, which was issued in April 2004 by the MHRA. However, Roche made shipments to this address before the wholesale dealer's licence was obtained.

The complainant noted that Roche had stated that as part of its ongoing discussions with the clinic, the pharmacist positioned himself as owning several



other clinics in the UK and that he proposed to set up another clinic. There was an existing clinic, which was about to close down as the owner was retiring. He asked Roche in 2004 for funds to support the set up costs. Roche had submitted that prior to making any such decision, as in any commercial organization, it had analysed whether the investment would be in the longer term interests of the company and concluded that it would. In addition it would benefit local patients who had used the clinic and others who would do so in the future. Roche therefore agreed to sponsor the clinic with £55,000 in two payments spread over 6 months as evidenced by confirmation from the owner and the invoice. Roche had submitted that this funding was not linked to the prescribing of Xenical. The funding was part paid – Roche paid the first instalment of £20,000 but the final payment of £35,000 was stopped when Roche was contacted by the MHRA and suspicions were raised about the legitimacy of the pharmacist. The complainant was astounded at this submission from Roche. Evidence provided to the Employment Tribunal included an internal Roche report in which the Roche employee stated that '[He] told me he would transfer all his patients over to Xenical in a phased switch if the price was right'. The Roche employee also advocated significant discounts to the price at which Xenical was normally sold and Roche later offered bonus packs to reduce the price. Another document submitted in evidence, described the private clinic funding proposal and stated that the owner requested the company's help in supporting the purchase of particular clinics, adding that he believed 'this undoubtedly makes switching to Xenical easier'.

### **ROCHE'S COMMENTS ON THE REPORT FROM THE PANEL**

Roche restricted its comments to the matter of funding the slimming clinic. Roche explained that the local medical representative's proposals for funding had been rejected a number of times before he found two people in the company willing to agree to it. Those involved had effectively circumvented the normal approval process. The funding was eventually agreed without medical sign off. Roche submitted that since then it had substantially changed its approval procedures and awareness of the Code and its requirements was now much better throughout the company.

### **JURISDICTION**

The week prior to the appeal Roche submitted that, as set out in its appeal, the commercial supply of Xenical to the clinic in question did not constitute promotion, and as such the Code was not applicable and the Panel had no jurisdiction. Roche considered it was for the MHRA rather than the Authority to take action if such supply was considered inappropriate (Roche rejected the contention that this was the case). Roche had

cooperated with the MHRA in its prosecution of the owner of the clinic, and Roche's processes relating to the opening of new customer accounts had been reviewed in a Good Manufacturing Practice (GMP) audit independent of the MHRA prosecution. Roche submitted that the Authority had exceeded its powers by assuming jurisdiction in this matter.

The Chairman of the Appeal Board considered the points raised by Roche very carefully. In his view the question of jurisdiction was a matter of law upon which he needed to give a ruling rather than a matter of facts or merits which would be a matter for the Appeal Board. The Chairman decided to invite both parties to make brief submissions on this point at the start of the proceedings after which he would rule upon the question of jurisdiction. Both parties were so advised and a copy of Roche's letter was provided to the complainant in advance of the appeal hearing.

At the hearing Roche's representatives repeated the company's submission as detailed above. The complainant disagreed with Roche's arguments and submitted, *inter alia*, that the funding of the slimming clinics and the supply of Xenical were so inextricably linked that the latter amounted to the promotion of the product and was thus subject to the Code.

The Chairman noted that despite the 2001 and 2003 Codes being applicable to the matters at issue, the substance of Clause 1, which covered the scope of the Code, remained the same. Clause 1.1 stated that the 'Code applies to the promotion of medicines' and further 'to a number of areas which are non-promotional'. Clause 1.2 defined promotion as 'any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines'. The Chairman thus considered that promotion was wider than the obvious understanding of advertisements and marketing, its definition was not restrictive and the examples stated in the Code were not exhaustive. The Shorter Oxford English Dictionary, 2nd volume, defined promotion as 'advancement in position' or 'action of helping forward'. The Chairman considered that for there to be commercial supply there must be a commercial relationship. In this case the extent of the commercial relationship was illustrated by the fact that Roche admitted that it had a number of dealings with the diet clinics. In particular the Chairman noted Roche had sent an employee to a clinic in 2003 on a fact-finding exercise. Roche carried on a business relationship thereafter. The Chairman considered that the act of conducting a business relationship with customers in order to further the sale of prescription only medicines could properly be said to be advancing or helping forward an activity undertaken by a pharmaceutical company which promoted the prescription, supply, sale or administration of its medicines. On facts of this particular case the supply of Xenical came within the scope of the Code and the Authority had jurisdiction in the matter.

## APPEAL BOARD RULING

The Appeal Board noted Roche's submission that the MHRA had seen all related Roche internal documents and had cleared the company of any wrong-doing. The Appeal Board noted Roche's submission that it was a victim of criminal activity. The Appeal Board's role was to consider the matter in relation to the Code which was not the role of the MHRA.

The Appeal Board noted that the activities had taken place in 2003 and 2004; the 2001 and 2003 Codes were thus applicable. With regard to Clause 2, there was no difference between the requirements in the 2001 and 2003 Codes. Clause 9.1 in both Codes required high standards to be maintained. Other wording in Clause 9.1 of the 2001 Code had become Clause 9.2 in the 2003 Code. Taking all these factors into account, the Appeal Board decided it would make its rulings in relation to the 2003 Code using the Constitution and Procedure in the 2006 Code.

The Appeal Board noted Roche's concerns about the implications of this case on the interpretation of current UK legislation for wholesaler distribution. The Appeal Board did not agree. This case turned on its own particular facts.

The Appeal Board noted Roche's submission that the supply of Xenical to private slimming clinics was a new area of business for the company. The Appeal Board also noted that internal emails from 2000 onward showed staff concern over the legality of supplying prescription only medicines to such organizations but Roche indicated at the hearing that its legal department had not agreed with the basis of this concern and had concluded that such supply was legal.

The complainant had supplied a copy of a statement from a Roche employee which stated that although he had met the doctor who supervised the clinics once in January 2002, this had been at the doctor's own clinic. This meeting was to ensure that as lead clinician the doctor was familiar with Xenical, the prescribing guidelines and ongoing patient support programmes. All the relevant promotional material was said to be supplied at this meeting. Other than that one meeting with the doctor all other meetings had been with the owner of the clinics, who Roche believed was a pharmacist although it did not have, and never sought, any proof of this. The Appeal Board noted that the Xenical New Account Proposal Form for the Diet Centre, which included the supervising doctor's name and GMC number, did not need to be signed by him and nor was the form dated. The Appeal Board considered that the investigations carried out by Roche in the first instance, when it set up the account, should have been more rigorous but nonetheless it did not consider that Roche's actions were entirely unreasonable given that it appeared satisfied that a qualified health professional was responsible for the operation of the clinics.

The Appeal Board noted that in 2003 Roche became concerned that the large volume of Xenical being provided to the Diet Clinic might indicate that the product was being sold on the grey market. The company thus sent one of its employees to the clinic to act as a new patient seeking help with weight loss. That employee was seen only by the owner who 'eventually' agreed to prescribe him Xenical. The Appeal Board was extremely concerned that a prescription only medicine had been supplied to a patient by someone who Roche knew was not a doctor. The Appeal Board noted that although Roche now submitted that the company assumed that the owner was supplying the Xenical according to a Patient Group Direction Roche provided no evidence to support such an assumption. This raised serious concerns with regard to patients' safety. The visit report ended with the statement that it was 'difficult to see how he/they can be using much Xenical – although it is of course possible that the partner might be a huge fan'.

The Appeal Board noted that although Roche continued to be concerned that the volume of Xenical sold to the Diet Clinic was more than that dispensed, it maintained but capped the amount it would sell to the clinic in 2003. In December of that year a business analyst from Roche visited the Diet Clinic again to ascertain whether Xenical was being dispensed from the clinic or sold onto the grey market. There was no evidence that the Xenical was being sold on locally and thus the analyst advised against closing down trading terms with the clinic, convinced that it had a significant number of patients and that a significant number of them received Xenical. During the course of that visit the Roche employee was shown patient records which he believed were valid and provided evidence to show that it was appropriate to continue to supply Xenical to the clinic. In March 2005 the MHRA advised Roche that it was investigating allegations of criminal activity at the slimming clinic and asked the company to continue supplying Xenical whilst its investigations were ongoing.

The Appeal Board was extremely concerned about the supply of Xenical to the diet clinic. In the Appeal Board's view, by the end of May 2003 the company should have strongly suspected that the manner in which Xenical was prescribed at the clinic was inappropriate and possibly prejudicial to patient safety. The company, however, appeared to act principally with regard to commercial concerns to ensure that Xenical was not entering the grey market. No other action was taken. The Appeal Board acknowledged that from March 2005 Roche had co-operated with the MHRA and in that regard it had to continue to supply the clinics. Nonetheless the Appeal Board considered that between May 2003 and March 2005 Roche had not upheld high standards with regard to its supply of Xenical to the diet clinic. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The Appeal Board further considered that Roche's actions had brought discredit upon, and reduced confidence in, the

pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on both points was unsuccessful.

The Appeal Board noted the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure was with respect to both the supply of Xenical and the funding of the new slimming clinic. Roche had not appealed the Panel's rulings of breaches of Clauses 2, 9.1, and 18.1 of the 2003 Code in relation to its funding of the clinic to the sum of £55,000 of which £20,000 had been paid.

The Appeal Board was extremely concerned about this case, particularly with reference to Roche's disregard for patient care and its lack of action in 2003. The payment for the purchase of the clinic was clearly linked to the prescribing of Xenical and thus was totally unacceptable. The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure that Roche would be publicly reprimanded. The Appeal Board noted that Roche had already been audited three times in relation to Case AUTH/1819/4/06 and another audit in that case was pending. The Appeal Board decided, in accordance with Paragraph 12.2 of the Constitution and Procedure, to report Roche to the ABPI Board of Management with the recommendation that the company be suspended from membership of the ABPI.

#### **CASE AUTH/2100/2/08**

The Financial Times (FT) of 12 February 2008 carried an article critical of the marketing of Xenical (orlistat) by Roche Products Limited. In accordance with established practice the matter was taken up as a complaint under the Code.

#### **COMPLAINT**

The article alleged that Roche had sold large quantities of Xenical (a prescription only medicine) to the operator of a chain of private UK diet clinics in spite of suspicion at one stage that the product was being sold illegally. Roche had agreed to provide £55,000 for the purchase of another diet clinic to the individual involved in the clinics who was subsequently convicted of offences against the Medicines Act 1968.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 9.1, 17 and 18.

The author of the FT article did not participate in the procedure.

#### **RESPONSE**

Roche stated that the background to this complaint was complex and spanned the last five years.

- Roche and other pharmaceutical manufacturers

were the victims of criminal activity relating to a group of private diet clinics.

- From March 2005 Roche supported the Medicines and Healthcare products Regulatory Agency (MHRA) at all levels to provide information and intelligence for it to build a criminal case against two individuals. One had posed as a pharmacist and treated patients for obesity, including the provision of prescription medicines.
- It later transpired that the latter was employed by another pharmaceutical company as a medical sales representative and the other was his previous line manager selling their company's anti-obesity treatment.
- The case was heard in court (November 2007) and both defendants pleaded guilty (one to five offences and the other to one offence against the Medicines Act) and awaited sentencing.
- Over the course of its investigation the MHRA had seen all related Roche internal documents and had cleared Roche of any wrong-doing in relation to this complex case. In fact the MHRA had thanked Roche for its co-operation and support to help it prosecute these individuals.
- Similarly, Roche had been engaged in an employment tribunal with the complainant in Case AUTH/2099/2/08 for the last 3 years who claimed her dismissal from the company was a result of 'whistle blowing' when questions about the diet clinic came to light – something which Roche strongly refuted. The employment tribunal found that as Roche did not follow the correct dismissal process the complainant was unfairly dismissed. Roche acknowledged the unfair dismissal, however this was not for whistle blowing. The claimant's whistle blowing claim was therefore not upheld. The employment tribunal was still ongoing as the claimant had appealed the ruling.
- Thus this was a very complex situation of which detailed information had already been heard by a criminal court of law, an employment tribunal, and full documentation had been reviewed by the MHRA.

This response would address every Code matter raised in the article and in relation to Clauses 2, 9.1, 17 and 18.

Roche explained that from 2002 it took the first step into a new market place – that of private slimming clinics. Roche was in contact with over 150 private slimming clinics; however it was approached by the diet clinic in question in April 2002 to provide support. Roche understood that the owner was a pharmacist and that he owned a group of weight management clinics.

A Xenical New Account Proposal Form was completed which provided the name and General Medical Council (GMC) number of the doctor working at the clinic. Roche had met the doctor and pharmacist on a regular basis, though the pharmacist clearly drove the initiative. In addition, Roche was provided with the list of diet clinics that made up the group, the staffing at these clinics as

well as the opening hours. The diet clinic in question requested Roche supplied Xenical directly and in line with standard procedure; the GMC number of the doctor was confirmed and Roche therefore authorised direct distribution of stock, not in breach of Clause 17.

When Roche entered any new market it was standard commercial practice for it to closely monitor progress. Roche noted higher than expected volumes of Xenical being sold to the diet clinic and visited it several times to check that it was providing medicine to patients and not selling Xenical on to the grey market. Roche had no reason to believe that the staff running the clinic were not legitimate and this was not questioned. Roche monitored sales of Xenical in neighbouring regions and noted no change in sales or sales pattern.

Roche sent some of its staff to question the clinic and to review its data and also sent someone to pose as a patient. The rationale for this was to check that patients were consulted at the clinic and Xenical was used directly with patients and not being sold on. Roche had no knowledge or reason to suspect the owner of any criminal activities and its investigations were not into this aspect of the clinic's activities. Following Roche's investigations it was satisfied that the clinics were run properly and the demand for Xenical was appropriate for the local population. Roche provided copies of advertisements placed in local papers which suggested that the clinic worked closely with local surgeries and the community. On that basis Roche continued to supply the clinic, although it monitored and capped the quantity it supplied.

Roche's member of staff who posed as a patient was provided with a pack of Xenical by the pharmacist. Roche did not question this as this was not unusual because there were processes where health professionals other than doctors could provide prescription only medicines to patients - these included patient group directions (PGDs), and supplementary prescribing. With a PGD the qualified health professionals who might supply or administer medicines under such an arrangement included, *inter alia*, pharmacists. As Roche had stated previously, it had no reason to question the credibility of the pharmacist and the member of staff who attended the clinic did not investigate this. Following the MHRA investigation it was discovered that the clinic did not hold a PGD at the time.

The FT article quoted from an internal report of this visit. This document was for internal use only and Roche agreed that it had been written in a flippant way. However given that this member of staff posed as a patient to check if patients were seen and that Xenical was used by the clinic ie it was not sold on to the grey market, this information, together with Roche's previous investigation led it to conclude that the clinic was genuine. Roche did not check the legality of the pharmacist.

The FT referred back to this internal report later in

the article and quoted Roche's member of staff as stating 'It is difficult to see how he/they can be using so much Xenical'. The FT did not print the sentence that followed, which was 'although it is of course possible that the partner might be a huge fan'.

Roche noted that it was standard commercial practice for a company to negotiate deals with its customers. The diet clinic negotiated a discount with Roche based on purchasing specific volumes. The discount was offered to all key slimming centres based on purchasing a specific volume. Within the contract there was no added incentive to increase the volume of usage to get a greater discount level.

As part of Roche's ongoing discussions, the pharmacist positioned himself as owning several other clinics in the UK, and that he proposed to set up another clinic which was otherwise about to close due to retirement. He approached Roche on a number of occasions and again in 2004 for funds to support the set up costs. Before it made any decision Roche analysed internally whether such an investment would be in its longer term interests and in this instance it concluded that it would. The provision of sponsorship needed to benefit patient care or benefit the NHS, and Roche thought it would benefit local patients who had used the clinic and others who would do so in future. Roche therefore agreed to sponsor the clinic for £55,000 with two payments spread over six months, as evidenced by letters from the pharmacist confirming the money was for sponsorship, paid in two parts.

An internal document referred to in the FT entitled 'Private Clinic Funding Proposal' was prepared by an ex-Roche employee as part of Roche's internal analysis. The pharmacist referred to the prescribing of Xenical. Roche noted that this was what the pharmacist alone said and was not a condition of funding, once that decision had been taken.

The FT article quoted '... is totally confident of, and gives his guarantee to an early and swift changeover to Xenical'. This quotation appeared in the Private Clinic Funding Proposal prepared by the ex-Roche employee and was not an official document, nor did it form the basis for the agreement to sponsor this initiative. Roche denied there was a link between the payment of sponsorship and the prescription of Xenical and denied this was a breach of Clause 18.

The funding was part paid - Roche paid the first instalment of £20,000 but the final payment of £35,000 was stopped when Roche was contacted by the MHRA and suspicions were raised about the possible criminal activities of the owner.

In March 2005 the Enforcement Division of the MHRA advised Roche that allegations of criminal activity at a diet clinic supplied by Roche and other pharmaceutical companies were being investigated. The MHRA asked Roche to continue supplying the



clinics with Xenical whilst the investigation was ongoing and Roche cooperated fully with this request and the investigation. Roche believed that in working with the MHRA, it had in fact maintained the high standards of the industry and it refuted a breach of Clause 9.1.

Roche was a victim of criminal activity in this case and had worked with the MHRA to ensure that there was sufficient evidence to convict the individuals involved. As victims of a crime, Roche did not consider its actions discredited the industry (Clause 2) and that high standards had been maintained (Clause 9.1). Roche had worked with the MHRA on the fraudulent behaviour and it had been investigated by the MHRA for any improper behaviour and cleared.

As a result of the criminal activity, Roche had subsequently changed its distribution mechanism and no longer supplied any private slimming clinic directly with medicines.

## **PANEL RULING**

The Panel noted Roche's submission that the MHRA had seen all related Roche internal documents and had cleared the company of any wrong-doing. The Panel noted Roche's submission that it was a victim of a criminal activity. The Panel's role was to consider the matter in relation to the Code which was not the role of the MHRA.

The Panel noted that the activities had taken place in 2003 and 2004. The applicable Codes would be the 2001 Code and the 2003 Code. With regard to Clauses 2, 18.1 and the supplementary information to Clause 18.1 referring to terms of trade (paragraph 1) there was no difference between these requirements in the 2001 and 2003 Codes. Clause 9.1 in both the 2001 Code and 2003 Code required that high standards be maintained. Other wording in Clause 9.1 of the 2001 Code had become Clause 9.2 in the 2003 Code. Taking all these factors into account the Panel decided to make its rulings in relation to the 2003 Code using the Constitution and Procedure in the 2006 Code.

The Panel noted that Roche had been asked to respond in relation to a number of clauses of the Code, including Clause 17. On reviewing Roche's response, the Panel did not consider that Clause 17 of the 2003 Code was relevant to the activities in question and thus that clause was not considered.

With regard to the supply of Xenical, the Panel was extremely concerned about the circumstances which had led to a prescription only medicine in effect being supplied to a person who was not a health professional and by that person to patients. The Panel noted Roche's submission that it had validated the GMC number of the doctor named on the new account proposal form. Roche provided details about the contract to supply Xenical to the owner in relation to other clinics also owned by

him. The document gave a contract price in relation to 1,500 packs per month which gave a saving to the clinic of approximately £17,280 per month compared with the NHS price. The document was signed and dated 17 August 2004 by the clinic owner. The Panel noted that the Code excluded terms of trade relating to prices, margins and discounts in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 as stated in the supplementary information to Clause 18.1. Discounts were in regular use by the industry on 1 January 1993 and thus were excluded from the Code. Thus no breach of Clause 18.1 of the Code was ruled.

The Panel noted that the contract did not stipulate that the professional status of the signatory be included. Roche had not confirmed the professional status of the clinic owner who Roche submitted had posed as a pharmacist. The Panel considered that in effect Roche had sold a prescription only medicine to a member of the public. The Panel was extremely concerned about the arrangements particularly given that someone from Roche had visited the diet clinic in May 2003 and had been seen by the owner. The report of that visit noted that to the lay person the owner would have passed as a doctor as he 'had the bag and sphygmomanometer etc to almost prove it'. The document used the term 'prescribed' and reported that the owner was clearly not a fan of Xenical. (This seemed at odds with another document on diet centre headed paper dated 18 April 2002 which set out a business proposal to offer Xenical as 'drug of choice' and asking for £6,000 to review the database and switch suitable patients to Xenical. The costs would be offset by revenue generated from Xenical and Roche was asked to provide some if not all of the funding for this to be undertaken in each of the clinics.) The Roche employee arranged to visit the clinic in June 2003 but no details of this visit, if it took place, were provided. The report stated that the Roche employee had paid £75 for a pack of Xenical and some herbal product was provided free of charge. Roche submitted that this visit was to learn more about the use of Xenical rather than the professional qualification of the owner. The Panel considered that companies needed to be particularly careful about the supply of medicines to private clinics. It noted that Roche had made enquiries about the doctor but not about the owner who claimed he was a pharmacist. The clinic visit report in May 2003 from the Roche employee should have led to further action on Roche's part and the company to question supply of Xenical to the clinic in 2004. The Panel considered that Roche had not paid sufficient attention to ensuring that the supply of its product to the private clinic in question was appropriate. Thus the Panel ruled a breach of Clause 9.1. The Panel considered that the arrangements brought discredit upon the pharmaceutical industry and a breach of Clause 2 of the Code was ruled.

The Panel noted that Roche had agreed to sponsor the new clinic initiative. According to documents

from the owner payment was to be in two parts, £20,000 payable in August 2004 and £35,000 in January 2005. According to Roche only £20,000 had been paid. The second payment had been halted following contact by the MHRA. A document prepared by a Roche employee headed 'Private Clinic Funding Proposal' was undated. It stated that if Roche agreed to the proposal it was hoped to complete purchase of the new diet clinic before the end of June 2003. The Private Clinic Funding Proposal also included sales analysis data for 2003 and 2004 showing the return on a £55,000 investment.

The Private Clinic Funding Proposal referred to the diet clinics as 'a real Xenical success story'. The owner was reported as having put enormous efforts into establishing Xenical across his group of clinics as the drug of choice for safe and effective long-term weight loss. At a meeting with two Roche employees the owner asked if Roche would be interested in supporting the purchase of particular clinics. The support would come in the form of Roche financially supporting the purchase. Previously the clinics acquired a stake in another diet clinic. That stake was said to have been bought under the proviso that patients were switched to Xenical in order to provide a more ethical and effective approach to the clinic. This led to an overwhelming increase in Xenical sales 'Thus showing that this winning formula can be easily introduced elsewhere'. The owner was said to be 'totally confident of and gives his guarantee of an early and swift changeover to Xenical' following an 'initial investment £55,000 – Roche'. Within a year the owner was 'confident that 2000 plus packs of Xenical a month will be prescribed at the ... diet clinic'.

The Panel noted that Roche had agreed to pay the money in August 2004. This meant that the applicable Code was the 2003 Code.

The supplementary information to Clause 18.1 of the 2003 Code stated that medical and educational goods and services could be provided if they enhanced patient care or benefited the NHS. The provision of such goods and services must not be done in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine.

The Panel considered that the proposed payment of £55,000 for the new diet clinic was linked to the use of Xenical. The proposal had been made on the basis that Xenical would become the medicine of choice at the clinic. The Private Clinic Funding Proposal stated that the current treatment guideline at the new clinic was not to use Xenical. The proposal produced by the Roche employee focussed only on the increased use of Xenical. There was nothing in the proposal to suggest that Roche had considered whether or not this was a medical or educational good or service. There was no evidence to show that Roche considered the proposal in relation to anything other than the

potential increased use of Xenical. It was difficult to see how providing £55,000 to an individual to purchase a private diet clinic was a medical and educational good or service that would enhance patient care or benefit the NHS as required by the Code. Thus the Panel ruled a breach of Clause 18.1 of the 2003 Code. The Panel did not consider that Roche had maintained high standards in relation to its agreement to provide an individual with £55,000. A breach of Clause 9.1 was also ruled. The Panel considered that the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel also considered that the circumstances warranted consideration by the Code of Practice Appeal Board in relation to the possibility of additional sanctions. Thus the Panel decided to report Roche to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

### **APPEAL BY ROCHE**

The appeal by Roche was identical to that submitted in relation to Case AUTH/2099/2/08.

### **APPEAL BOARD RULING**

Case AUTH/2100/2/08 was heard separately from Case AUTH/2099/2/08 which had immediately preceded it. Roche's appeal documentation was the same in both cases. At the hearing for Case AUTH/2100/2/08 the representatives from Roche stated that the Appeal Board could take into account Roche's submissions in Case AUTH/2099/2/08. The Appeal Board therefore considered that all submissions made in Case AUTH/2099/2/08 were deemed to have been made in Case AUTH/2100/2/08 as well.

The question of jurisdiction and applicable Codes had been settled in Case AUTH/2099/2/08.

The Appeal Board noted Roche's submission that the MHRA had seen all related Roche internal documents and had cleared the company of any wrong-doing. The Appeal Board noted Roche's submission that it was a victim of criminal activity. The Appeal Board's role was to consider the matter in relation to the Code which was not the role of the MHRA.

The Appeal Board noted Roche's concerns about the implications of this case on the interpretation of current UK legislation for wholesaler distribution. The Appeal Board did not agree. This case turned on its own particular facts.

The Appeal Board noted Roche's submission that the supply of Xenical to private slimming clinics was a new area of business for the company. The Appeal Board also noted that internal emails from

2000 onward showed staff concern over the legality of supplying prescription only medicines to such organizations but Roche indicated at the hearing that its legal department had not agreed with the basis of this concern and had concluded that such supply was legal.

In Case AUTH/2099/2/08 the complainant had supplied a copy of a statement from a Roche employee which stated that although he had met the doctor who supervised the clinics once in January 2002, this had been at the doctor's own clinic. This meeting was to ensure that as lead clinician the doctor was familiar with Xenical, the prescribing guidelines and ongoing patient support programmes. All the relevant promotional material was said to be supplied at this meeting. Other than that one meeting with the doctor all other meetings had been with the owner of the clinics who Roche believed was a pharmacist although it did not have, and never sought, any proof of this. The Appeal Board noted that the Xenical New Account Proposal Form for the diet centre, which included the supervising doctor's name and GMC number, did not need to be signed by him and nor was the form dated. The Appeal Board considered that the investigations carried out by Roche in the first instance, when it set up the account, should have been more rigorous but nonetheless it did not consider that Roche's actions were entirely unreasonable given that it appeared satisfied that a qualified health professional was responsible for the operation of the clinics.

The Appeal Board noted that in 2003 Roche became concerned that the large volume of Xenical being provided to the diet clinic might indicate that the product was being sold on the grey market. The company thus sent one of its employees to the clinic to act as a new patient seeking help with weight loss. That employee was seen only by the owner who 'eventually' agreed to prescribe him Xenical. The Appeal Board was extremely concerned that a prescription only medicine had been supplied to a patient by someone who Roche knew was not a doctor. The Appeal Board noted that although Roche now submitted that the company assumed that the owner was supplying the Xenical according to a Patient Group Direction Roche provided no evidence to support such an assumption. This raised serious concerns with regard to patients' safety. The visit report ended with the statement that it was 'difficult to see how he/they can be using much Xenical – although it is of course possible that the partner might be a huge fan'.

The Appeal Board noted that although Roche continued to be concerned that the volume of Xenical sold to the diet clinic was more than that dispensed, it maintained but capped the amount it would sell to the clinic in 2003. A document submitted in Case AUTH/2099/2/08 showed that in December of that year a business analyst from Roche visited the diet clinic again to ascertain whether Xenical was being dispensed from the

clinic or sold onto the grey market. There was no evidence that the Xenical was being sold on locally and thus the analyst advised against closing down trading terms with the clinic, convinced that it had a significant number of patients and that a significant number of them received Xenical. During the course of that visit the Roche employee was shown patient records which he believed were valid and provided evidence to show that it was appropriate to continue to supply Xenical to the clinic. In March 2005 the MHRA advised Roche that it was investigating allegations of criminal activity at the slimming clinic and asked the company to continue supplying Xenical whilst its investigations were ongoing.

The Appeal Board was extremely concerned about the supply of Xenical to the diet clinic. In the Appeal Board's view, by the end of May 2003 the company should have strongly suspected that the manner in which Xenical was prescribed at the clinic was inappropriate and possibly prejudicial to patient safety. The company, however, appeared to act principally with regard to commercial concerns to ensure that Xenical was not entering the grey market. No other action was taken. The Appeal Board acknowledged that from March 2005 Roche had co-operated with the MHRA and in that regard it had to continue to supply the clinics. Nonetheless the Appeal Board considered that between May 2003 and March 2005 Roche had not upheld high standards with regard to its supply of Xenical to the diet clinic. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The Appeal Board further considered that Roche's actions had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on both points was unsuccessful.

The Appeal Board noted the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure was with respect to both the supply of Xenical and the funding of the new slimming clinic. Roche had not appealed the Panel's rulings of breaches of Clauses 2, 9.1, and 18.1 of the 2003 Code in relation to its funding of the clinic to the sum of £55,000 of which £20,000 had been paid.

The Appeal Board was extremely concerned about this case, particularly with reference to Roche's disregard for patient care and its lack of action in 2003. The payment for the purchase of the clinic was clearly linked to the prescribing of Xenical and thus was totally unacceptable. The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure that Roche would be publicly reprimanded. The Appeal Board noted that Roche had already been audited three times in relation to Case AUTH/1819/4/06 and another audit in that case was pending. The Appeal Board decided, in accordance with Paragraph 12.2 of the Constitution and Procedure, to report Roche to the ABPI Board of Management with the recommendation that the company be suspended from membership of the ABPI.

\* \* \* \* \*

During its consideration of these cases the Appeal Board had reservations about the conduct of the doctor named on the account form. The Appeal Board was extremely mindful of the privileged nature of the material before it. The Appeal Board considered that in cases involving potential risk to patient safety it had a responsibility to notify the General Medical Council (GMC). It decided that once the cases were completed the case report and the article in the FT should be sent to the GMC.

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#### **CONSIDERATION BY THE ABPI BOARD OF MANAGEMENT**

The ABPI Board noted that Roche had been ruled in breach of Clauses 2, 9.1 and 18.1 of the Code. It also noted that Roche had been audited three times and a fourth audit was arranged for September in relation to another unrelated case.

The ABPI Board noted Roche's submission that the MHRA had not suggested any wrong-doing by Roche. However, it believed that funding of the clinic, and Roche not taking any action in relation to the supply of Xenical to the clinic following the visit

by the Roche employee posing as a new patient in 2003, were very serious matters. Both had been ruled in breach of the Code. The ABPI Board noted that the Appeal Board had recommended that Roche be suspended from membership of the ABPI and the ABPI Board concurred.

The ABPI Board agreed that Roche would be suspended from membership of the ABPI for a period of six months commencing 14 July 2008 with re-entry conditional upon the audit which the company was to undergo in September proving satisfactory to the Board.

#### **Case AUTH/2099/2/08**

**Complaint received 19 February 2008**

**Undertaking received 9 June 2008**

**ABPI Board consideration 17 June 2008**

#### **Case AUTH/2100/2/08**

**Proceedings commenced 19 February 2008**

**Undertaking received 9 June 2008**

**ABPI Board consideration 17 June 2008**

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