CASE AUTH/2805/12/15

BAYER v GUERBET

Offer of equipment

Bayer plc complained about its competitors, including Guerbet Laboratories, offering radiological contrast injection equipment on long term loan or as a gift to customers who agreed to purchase the company's contrast agent.

Bayer noted that a document produced by a purchasing organisation stated that three suppliers of radiological contrast media, including Guerbet, were offering the loan of injectors as part of a framework agreement based on defined-spend value through the respective suppliers' contrast.

Bayer alleged that a gift had been supplied, offered or promised to health professionals as an inducement to prescribe, supply, administer, recommend, buy or sell medicine. Bayer conceded that the Code did not prevent the offer of package deals whereby the purchase of a particular medicine was linked to the provision of certain associated benefits such as apparatus for administration, but stated that it considered a gift of that magnitude meant that the Code's additional requirement that the transaction as a whole must be fair and reasonable could not be satisfied. Bayer further alleged that such activities were likely to bring discredit upon, or reduce confidence in, the pharmaceutical industry in breach of Clause 2.

The detailed response from Guerbet is given below.

The Panel noted Guerbet's submission that its injectors were not offered on either long term loan or as a gift. Guerbet described the arrangement as a loan based on defined-spend value. The injectors remained the property of Guerbet and NHS customers could return the injector and stop buying contrast media from Guerbet at any point and Guerbet could refuse to supply the injector if it was not being used properly. The defined-spend value was based on the workload of the department. The Panel noted that a contract for the provision of a second soft bag injector (SBI) to a hospital in the form of a letter provided by Guerbet described the arrangement as the provision [of a second SBI injector], free of charge and on loan. Guerbet agreed not to increase the price of its contrast media for 5 years and the hospital agreed to commit to buying the range of contrast media required for the equipment for 5 years. The length of the agreement was 5 years from the date of the original agreement to provide the first injector. The Panel noted that each package deal would be negotiated individually with each NHS organisation.

The Panel noted that whilst Guerbet was the only company to provide contrast media pre-filled in a soft bag, other contrast media could be used with its injectors. Indeed such usage was common as there were supply issues with Guerbet's pre-filled bags. The Panel noted that the injector remained the property of Guerbet and an example of such loans for 3 and 5 years had been provided. The Panel queried whether a 5 year loan could be described as a short term loan and whether it was in fact a gift as described in the Code. The Panel noted that whilst it was unusual for customers not to meet their defined-spend, the continued loan of the injector appeared to be dependent on achieving it. In such circumstances the Panel did not consider that the arrangements could be described as fair and reasonable and a *bona fide* package deal as set out in the Code.

The Panel noted, however, that as submitted by Guerbet there was a complicating factor in that it had previously been decided that the relevant clause in the Code applied to individuals rather than organisations etc. The Panel noted its decision above in relation to the package deal but also noted that there was no evidence of any benefit to an individual. The Panel was thus obliged to rule no breach of the Code. The Panel, however, was concerned that the arrangements did not constitute a *bona fide* package deal; it appeared that the injectors remained with customers only for as long as they continued to buy Guerbet's medicines to at least a pre-defined value each year. The Panel considered that the loan of injectors conditional upon a minimum annual spend with regard to Guerbet's medicines was unacceptable. In that regard the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Bayer plc complained about the activities of its competitors in the radiological contrast field including Guerbet Laboratories Ltd.

COMPLAINT

The activity in question was the offer of contrast injection equipment on long term loan or as a gift to customers who agreed to purchase the company's contrast agent. Bayer stated that some of its NHS customers confirmed that these deals took place and others questioned the legitimacy of the activities which caused concern for the reputation of the industry.

By way of background Bayer explained that images obtained from radiographic procedures could be considerably enhanced by the use of contrast agents. Use of the agents during a series of scans precisely coordinated to the various phases of the contrast agent could improve the diagnostic capabilities of the procedure. In particular, the approach had been successfully applied to the injection of iodine-based contrast agents during computed tomography (CT) imaging and gadolinium-based contrast agents in magnetic resonance imaging (MRI). Exact coordination of the injection and contrast agent to the scanner cycle was a key part of the process. The use of a contrast injector linked to the scanner controls, enabling the rapid, exactly-timed delivery of contrast agents coordinated with the acquisition procedure had improved diagnosis and reduced costly repeat investigations. Many, but not all, of the UK companies involved in the manufacture and distribution of contrast agents also distributed contrast injectors. They were sophisticated items of equipment with an NHS price between £20,000 and £35,000, were not linked to a specific contrast agent and in some instances were third-party sourced.

Bayer stated that it had long been aware, but lacked proof, that several of its competitors had offered contrast injectors either as gifts or long term loans, to hospitals agreeing to sign a contract for supply of that company's contrast agents. Bayer became aware of a document, Implementation Brief for Supply of X-Ray Contrast Media, produced by a purchasing organisation that provided services to NHS and private hospitals in the UK. The implementation brief stated that three suppliers of radiological contrast media, one of which was Guerbet, were offering the loan of injectors as part of the framework agreement based on defined-spend value through the respective suppliers' contract.

Bayer had written to Guerbet stating that in its opinion such activity potentially breached Clause 18.1 in that a gift had been supplied, offered or promised to members of the health professions as an inducement to prescribe, supply, administer, recommend, buy or sell medicine. In its letter, Bayer conceded that the Code did not prevent the offer of package deals whereby the purchase of a particular medicine was linked to the provision of certain associated benefits such as apparatus for administration, but stated that it considered a gift of that magnitude meant that the Code's additional requirement that the transaction as a whole must be fair and reasonable could not be satisfied.

According to Bayer, Guerbet replied stating that it considered that an injector was apparatus for administration, the loan or gift of which was fair and reasonable and therefore exempted from the restrictions of Clause 18.1. Guerbet stated that as no individual health professional had benefitted from the offer meant that such a gift was not an inducement to prescribe. Guerbet did not deny that such gifts had been provided by its sales staff. Copies of inter-company dialogue were provided.

Bayer stated that some NHS customers had confirmed that inducements were being offered and an anonymised email from one such customer was enclosed which stated 'Guerbet give us the injectors as long as we use their contrast', implying that more than one injector might be on offer to customers agreeing to use Guerbet contrast agents in preference to others.

In Bayer's experience, contrast media injectors sold for around £20,000 to £35,000, depending on the model and the technology being used. The features offered varied widely but even basic models from the suppliers named by the purchasing organisation would not sell for less than £20,000. Additionally, there were installation and servicing costs which would normally be charged to the customer. Bayer reiterated that the offer of injectors in the above price range as part of a package deal was neither fair nor reasonable.

In recent years Bayer had become increasingly concerned about the activities of its competitors in the field and was aware that they had been in activities proscribed by the Code, but had been frustrated by the lack of documentary evidence to support an approach to Guerbet or the Authority. Bayer stated that in this instance the purchasing organisation had fortunately provided it with publicly available evidence. That the offer of inducement had been made on behalf of Guerbet by a third party did not, in Bayer's opinion, provide an adequate defence against the charge.

Bayer had little doubt that the provision of contrast injectors valued between £20,000 and £35,000 by Guerbet to health authority departments as part of a package deal for contrast agents was not a fair or reasonable arrangement and therefore was in breach of Clause 18.1. Bayer alleged that such activities were likely to bring discredit upon, or reduce confidence in the pharmaceutical industry in breach of Clause 2.

RESPONSE

Guerbet stated that whilst Bayer had clearly explained the purpose of contrast media and the benefit of using an injector to administer it, it failed to disclose that it had a strong interest in selling injectors, in fact, Bayer was the market leader in injectors (trading in the name of Medrad) and it benefitted greatly from sales of medical disposables which were needed for the use of its injectors. Bayer also failed to disclose that it had withdrawn its contrast media Ultravist (iopromide) from the UK market a few years ago, probably due to a profit issue as the product was still available in other parts of the world where prices were generally better. Therefore, it was clear that Bayer was not able to offer the same services as other suppliers and was facing stiff challenges to the sale of its injectors.

The letter from Bayer to Guerbet Laboratories in October 2015 included the assumptions that: Guerbet was aware of the document provided by the purchasing organisation; all injectors were priced around £20,000 or more; and Guerbet was giving injectors away as gifts.

Guerbet submitted that Bayer had no knowledge about the financial charges incurred and what customers paid for the use of Guerbet injectors; it had no knowledge about the cost of Guerbet's injectors and the ownership of the injectors. Guerbet did not see why it needed to disclose its business arrangements to Bayer just as it did not expect Bayer to disclose its business dealings to Guerbet.

In response to a request from the case preparation manager for a full response, Guerbet submitted that it had no further comment to add, however it would review its arrangement with the existing customer base to determine if it had breached the Code and rectify those cases if necessary. Guerbet suggested that the Panel reach out to customers of Guerbet whom it thought could have been misled to enter into such an arrangement in order to get a different perspective on the matter.

In response to a request for further information from the Panel, Guerbet submitted that Bayer had accused it of offering the long term loan or gift of contrast injection equipment. Guerbet clarified that the injectors remained the property of Guerbet and were therefore not a gift, neither were they on long term loan. NHS customers were free to return the injector and stop buying contrast media from Guerbet at any point and Guerbet could refuse to supply the injector if it was not being used properly.

Guerbet noted that Bayer implied the cost of contrast injectors ranged between £20,000 and £35,000. The NHS supply chain published price list was a national framework price list which all NHS trusts in the country were able to use. The prices were significantly lower compared to what Bayer claimed it was worth.

Guerbet stated that Bayer repeatedly implied that via the purchasing organisation, Guerbet had offered injectors as a gift or on long term loan to induce the sales of contrast media; there was no explicit nor implied message within the purchasing organisation implementation brief that this was so. Firstly, the injector was offered on loan based on defined-spend value and therefore it was not a gift. Secondly, the framework agreement was being reviewed and renewed every 2-3 years following an open tender exercise; NHS trusts were not obliged to stay with Guerbet's product and could choose any supplier listed on the Framework Agreement and Bayer's accusation was unfounded.

Bayer claimed that some NHS customers had confirmed that inducements were being offered and provided an email exchange between a Guerbet customer and Bayer's representative as evidence. Guerbet stated that the email was dated after Bayer had sent the original complaint to Guerbet and queried if Bayer had actively solicited the email in order to support its claim. The email clearly stated that the NHS trust's concern was that it was not able to purchase two CT injectors, presumably from Bayer, due to financial constraints. Although, the email used the word 'give', Guerbet assumed that it was a figure of speech and possible misunderstanding on the part of the author. The injector belonged to Guerbet and continued to do so. Guerbet was prepared to clarify the use of the word 'give' with the author if Bayer provided the name of the person concerned, however, Guerbet queried whether it was a tactic used by the author to fend off the overly zealous Bayer representative.

To further demonstrate that the provision of its injector was not a gift or long term loan, Guerbet shared with the PMCPA prices which NHS customers had to pay for the use of one of its contrast media compared to products for a similar purpose from competitors. Guerbet insisted that this was confidential information that was not disclosed to Bayer or any other company. When iobitridol in a soft bag was administered using Guerbet's soft bag injector, it offered customers the convenience of not having to transfer the contrast solution into an empty syringe or container which meant saving time for preparation, reduced chances of contamination and there was less waste material to dispose of following administration among other benefits. Guerbet submitted that NHS customers were not buying its contrast media because they were induced by the offer of a free-to-use injector but because they were looking at the total cost of contrast media administration and the time saving and aseptic practice that the system (contrast media + injectors) offered. Guerbet submitted that contrary to Bayer's accusation, its practice was well within the permitted scope of Clause 18.1.

Guerbet submitted that the purchasing organisation supported over 400 public and private sector organisations throughout the UK, partnering with them to deliver innovative and best value procurement solutions. Guerbet was a manufacturer and supplier of contrast media and medical devices, it participated in the tender exercise called for by the purchasing organisation on behalf of its customers. Following this, the products and services offered by Guerbet were deemed to be competitive and as bringing value to the NHS trusts. Therefore Guerbet was accepted as one of the framework suppliers together with three other contrast media manufacturers, with the exception of Bayer, which had been delisted.

The purchasing organisation did not purchase from Guerbet and Guerbet did not supply it. Whilst the purchasing organisation acted on behalf of its customers, NHS trusts, to negotiate and secure the best deal available in the market, Guerbet sought to expand business by offering the best possible products and services in a competitive manner.

Guerbet reiterated that the purchasing organisation did not consult it before issuing the Legal Services Framework Brief, the first time it was seen was with Bayer's complaint dated 16 October 2015. Guerbet submitted that it was an internal document, contrary to Bayer's claim that it was publicly available. Guerbet's customers were NHS trusts and the arrangements for the supply of contrast media and injectors were between Guerbet and the respective trust, the purchasing organisation had acted on behalf of the participating trust to put together a pricing framework agreement but the required spend value for each account was subject to negotiation between Guerbet and the respective trust.
Guerbet submitted that the supply of injectors in conjunction with sales of contrast media could be categorised under the supplementary information for Clause 18.1 Package Deals.

Guerbet further stressed the legitimacy of such a deal by explaining that the NHS trusts were provided with options, in this case there were three other companies who offered similar packages, each with its own unique features. For example the nature of the contrast media (viscosity, hydrophilicity, osmolality, concentration etc); pack sizes (50ml, 75ml, 100ml, 150ml, 200ml etc); presentation type (pre-filled syringe, soft bag, glass bottle, plastic bottle); clinician preference.

Depending on the type of presentation, some added advantages could be derived from the use of a specific injector. For example, the efficiency of using Guerbet contrast media which were supplied in soft bags, was greatly enhanced if they were used with a soft bag injector. However, the NHS trust would have to pay a higher price for the contrast media for the added convenience and improved aseptic handling of the contrast solution.

Guerbet also noted that the provision of an injector did not personally benefit any individual NHS customer, except to enable them to deliver the service they were expected to deliver under the constraint of not having sufficient funding to acquire new equipment, increased workload and no additional manpower.

Therefore, Guerbet disagreed with Bayer's allegation that provision of its soft bag injector was an inducement to purchase its contrast media; it was a necessity if the customer wanted to fully capitalize the advantages of having contrast media in a soft bag and Guerbet denied a breach of Clause 18.1.

In response to a further request from the Panel for more information, Guerbet explained that the defined-spend value was calculated based on the workload of the department either independently or collectively if there was more than one site. The department was generally expected to perform approximately 3,000 contrast enhanced scans per site per year. As prices of contrast media were pre-determined and confirmed by the framework agreement, the expected revenue from each injector installed could be estimated.

Guerbet provided a contract agreement it had with a named hospital as an example and submitted that it was uncommon for hospitals to experience a sudden significant reduction in workload. Therefore if pre-installation assessment was done correctly with both parties being transparent and honest about existing workload and expectations, the chances of not meeting defined-spend was unusual. In the event that an NHS trust bought significantly less contrast media from Guerbet it could only mean that it had found a cheaper alternative. Such an example was provided wherein a customer asked Guerbet to remove its injector from the department as it was no longer needed.

Guerbet submitted that NHS employees took good care of equipment which was entrusted to their use so it did not see injectors being abused or misused such that it warranted removal of an injector which could jeopardise continuous operation of the department.

Guerbet submitted that it was the only company that provided contrast media pre-filled in a soft bag; it was a patented technology. However, other companies' contrast media could be used with its injector if it was transferred into empty bags which were commercially available. The use of contrast media from other pharmaceutical companies was common over the past 18 months as Guerbet had supply issues with its pre-filled bags.

The injector remained the property of Guerbet, however, if a hospital wished to purchase it, it was open to discussions. Guerbet had had no such request thus far.

PANEL RULING

The Panel noted that the relevant Clauses were identical in both the 2015 and 2016 versions of the Code. The Panel thus considered this matter under the 2016 version of the Code.

The Panel noted Bayer's allegation that the provision of contrast injectors valued between £20,000 and £35,000 as part of a package deal for contrast agents was not a fair or reasonable arrangement and alleged, *inter alia*, a breach of Clause 18.1. The Panel noted Guerbet's submission that it had not seen the purchasing organisation report provided by Bayer prior to the complaint. In the Panel's view Bayer's allegation was as stated above. The purchasing organisation report was provided as general evidence that package deals were being offered. The Panel noted Guerbet's submission that it negotiated each package deal directly with the relevant NHS body.

The Panel noted that Clause 18.1 prohibited the provision, offer or promise of a gift, pecuniary advantage or benefit to health professionals or other relevant decision makers as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Its supplementary information Long term or Permanent Loan stated that the requirements of Clause 18.1 could not be avoided by the provision of items on long term or permanent loan. Such items would be regarded as gifts and subject to the requirements of that clause. The supplementary information Package Deals stated that Clause 18.1 did not prevent the offer of package deals which were commercial arrangements whereby the purchase of a particular medicine was linked to the provision of certain benefits as part of the purchase price. Examples given included apparatus for administration, the provision of training on its administration or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

The Panel noted Guerbet's submission that its injectors were not offered on either long term loan or as a gift. Guerbet described the arrangement as a loan based on defined-spend value. The injectors remained the property of Guerbet and NHS customers could return the injector and stop buying contrast media from Guerbet at any point and Guerbet could refuse to supply the injector if it was not being used properly. The defined-spend value was based on the workload of the department. The Panel noted that a 2012 contract for the provision of a second SBI injector to a hospital in the form of a letter provided by Guerbet described the arrangement as the provision [of a second

SBI injector], free of charge and on loan. Guerbet agreed not to increase the price of its contrast media for 5 years and the hospital agreed to commit to buying the range of contrast media required for the equipment for 5 years. The length of the agreement was 5 years from March 2011, the date of the original agreement to provide the first injector. The Panel noted that each package deal would be negotiated individually with each NHS organisation.

The Panel noted that whilst Guerbet was the only company to provide contrast media pre-filled in a soft bag, other contrast media could be used with its injectors. Indeed such usage was common as there were supply issues with Guerbet's pre-filled bags. The Panel noted that the injector remained the property of Guerbet and an example of such loans for 3 and 5 years had been provided. The Panel queried whether a 5 year loan could be described as a short term loan and whether it was in fact a gift as described in the supplementary information to Clause 18.1. The Panel noted that whilst it was unusual for customers not to meet their defined-spend, the continued loan of the injector appeared to be dependent on achieving it. In such circumstances the Panel did not consider that the arrangements could be described as fair and reasonable and a *bona fide* package deal as set out in the supplementary information to Clause 18.1.

The Panel noted, however, that as submitted by Guerbet there was a complicating factor in that it had previously been decided that Clause 18.1 applied to individuals rather than organisations etc. The Panel noted its decision above in relation to the package deal but also noted that there was no evidence of any benefit to an individual. The Panel was thus obliged to rule no breach of Clause 18.1. The Panel, however, was concerned that the arrangements did not constitute a *bona fide* package deal; it appeared that the injectors remained with customers only for as long as they continued to buy Guerbet's medicines to at least a pre-defined value each year. The copy of an agreement provided by Guerbet showed the defined-spend for two injectors. The Panel considered that the loan of injectors conditional upon a minimum annual spend with regard to Guerbet's medicines was unacceptable. In that regard the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **1 December 2015**

Case completed **4 May 2016**