BAYER v MALLINCKRODT

Offer of equipment

Bayer plc complained about its competitors, including Mallinckrodt UK Commercial, 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 Mallinckrodt, 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 Mallinckrodt is given below.

The Panel noted Bayer's allegation that the provision of contrast injectors valued between £20k and £35k as part of a package deal for contrast agents was not a fair or reasonable arrangement in breach of the Code.

The Panel noted Mallinckrodt's submission that its injectors were not offered on long term or permanent loan.

The Panel noted Mallinckrodt's explanation that package deals (mainly for 2-3 years) were developed based on customer usage requirements to ensure that the provision of an injector complied with the Code. Provided the commitment to volume of Mallinckrodt product was achieved, customers could choose alternative contrast media suppliers and retain the injector. Package deals were based on the value of the equipment being a given percentage of the total value of consumables/contrast media which Mallinckrodt submitted was in accordance with NHS terms and conditions. The ownership of the injector transferred to the customer on delivery as part of the total package deal and was inclusive of the purchase price of the pre-filled syringes. Mallinckrodt submitted that this was fair and reasonable because the equipment was necessary for performing clinical tasks as outlined in the Code.

The Panel noted that according to the template contract, in return for the payment of the equipment price, the service fee and the purchase of an agreed volume of consumables at agreed prices, Mallinckrodt agreed to supply the injector and services to the customer. The customer acknowledged that the level of discount was offered on the basis of the total value of the package deal. The Panel noted that the template was inconsistent in some regards; it referred to title passing to the customer on payment in full of the equipment price although Mallinckrodt had confirmed that ownership passed on delivery. The Panel noted Mallinckrodt's submission that there was no contractual or other mechanism to recover the investment if insufficient volume was purchased and that currently the company did not wish to impose a financial penalty for failing to use sufficient product and not achieving the threshold. The Panel noted that Section 9 set out a termination clause by which either party could give notice for breach of a material term. The Panel noted that in effect under the contract the customer paid for the injector at an agreed level of discount which was related to the total value of the package deal.

The Panel noted Mallinckrodt's submission that it had only one imaging injector with a price anywhere near the £20k quoted by Bayer. This injector had never been placed on a package deal since end users had decided not to use the Mallinckrodt contrast media in question.

The Panel noted that the relevant supplementary information to the Code referred to the provision of apparatus for administration. The Panel noted that the injector could be used not only with Mallinckrodt's contrast media but also with others. Ownership apparently passed to the customer upon delivery although the Panel noted its comments on the contract above. The injector would not be removed if agreed volumes were not achieved and it appeared that the total cost paid by the customer included an element which reflected the discounted cost of the injector. In the Panel's view the overall agreement did not appear to be unfair or unreasonable and thus it considered that the arrangements constituted a *bona fide* package deal.

The Panel noted that, as submitted by Mallinckrodt, 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 that the arrangements were a *bona fide* package deal and further that there was no benefit to an individual. In any event Mallinckrodt had not

provided an injector which would sell for £20k to £35k as alleged. The Panel ruled no breach of the Code. Further, the Panel ruled no breach of Clause 2.

Bayer plc complained about the activities of its competitors in the radiological contrast field including Mallinckrodt UK Commercial 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 Mallinckrodt, 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 Mallinckrodt 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, Mallinckrodt 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. Mallinckrodt did not deny that such gifts had been provided by its sales staff.

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 Mallinckrodt 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 Mallinckrodt 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 Mallinckrodt 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

Mallinckrodt submitted that it manufactured and supplied contrast media and injectors for diagnostic purposes. In November 2015, Mallinckrodt CMDS (just injectors and contrast media) separated from Mallinckrodt Pharmaceuticals and transferred to Guerbet Laboratories under a share transfer. Currently, it continued to trade legally as Mallinckrodt UK Commercial Ltd and would continue to do so for several months. Mallinckrodt accepted that once it legally became Guerbet, it would fall under the obligations to follow the Code unless it was deemed unnecessary to do so for reasons such as administrative burden.

Mallinckrodt submitted that its response below was not an agreement to sign up to the Code; as a non-

member it was not required to provide a formal response but as it had core values of quality and integrity, it had operated within the guidelines of the Code to the best of its ability since October 2007 recognising that it was best practice.

Mallinckrodt noted that it could not influence the rhetoric used by customers. Despite its awareness of the issue at hand, the purchasing organisation had recently re-tendered, requesting details for injectors on loan/lease or purchase. Mallinckrodt provided a copy of its most recent response to the purchasing organisation and submitted that a request for a loan injector was either incorrect use of language or an unsolicited request to find the most cost effective way for end users to use their product of choice.

Market evolution and dynamics

Mallinckrodt submitted that it had been a key player in developing contrast media molecules and the use of contrast media since the launch of Conray (iothalamate meglumine), an ionic contrast medium, in 1962 followed by Optiray (ioversol), a non-ionic, low osmolar contrast medium, in 1989. With the acquisition of Liebel Flarshiem in 1996 it became the first company to offer both the injector and contrast medium. Mallinckrodt launched the first pre-filled syringe containing Optiray in 1996 and this had since been offered as a choice for departments preferring a pre-filled syringe option. Bayer had not succeeded in launching a pre-filled Ultravist (iopromide) syringe. It was widely recognised that pre-filled syringes offered advantages for user and patient, however this could be a more expensive option and as cost constraints had become priority for the NHS in recent years, Optiray had lost, not gained market share as one would expect from tactics which were allegedly designed to induce prescribing. Evidence was provided (usage data provided by European Contrast Media Group) to show that market share had mostly been lost to another named company.

Bayer became the second company to offer both injectors and contrast media in or around 2006. There were distinct advantages in doing so such as an acute awareness of pharmacovigilance issues surrounding injecting a pharmaceutical and the compliance guidelines governing these. It was clear from the activities of companies (mainly distributors, and at this time, excluding Bayer) which offered injectors without the pharmaceutical, that compliance was far greater when a pharmaceutical was involved.

Although Mallinckrodt had not seen official notification, it was widely understood that Bayer had recently withdrawn Ultravist in the UK and customers had sought alternative contrast medium. Since injectors had a life of 7 to 10 years, there would be significant accounts in the UK which would have continued to use the 'Medrad' injector from Bayer with alternative contrast media. Bayer would continue to receive revenue from the sale of disposals for those which were generally proprietary. Again, it was not a scenario in which an injector could be allegedly used to 'bribe or induce' a customer into using Mallinckrodt contrast media, since the pre-filled syringes did not fit and there were cheaper alternatives to Optiray in glass bottles, which was not price competitive in the UK. Mallinckrodt referred to a diagram of an injector with a pre-filled syringe and an empty syringe in situ to assist in understanding the machinery and how it could be used with alternative contrast media.

Clinical choice and presentation preference

Mallinckrodt submitted that Bayer failed to note that there were various presentations to administer contrast media (eg vials with empty syringes, soft bags, pre-filled syringes) which tended to be specific to certain injectors. Mallinckrodt submitted that injector placements based on the sale of related consumables and disposables were far more commonplace although it reserved to make an allegation against any specific company. The type of presentation tended to be a clinical choice based on technique, efficiency and infection control safety standards rather than the functionality of an injector. If a customer used a pre-filled syringe, it was a clinical decision for which they had limited options regarding the injector. Therefore the placement of an injector, whether loaned (which Mallinckrodt did not do), rented (which it also did not do but it was seeking legal advice on the feasibility of this option), package deal (which Mallinckrodt could offer based on a compliance calculation as a percentage of the total deal) or sale was secondary to the choice of presentation. A customer might choose a pre-filled syringe over a vial and empty syringe to save time or due to local hospital directives in line with advice from the National Patient Safety Agency that injectable medicines were pre-filled wherever possible. A customer might also choose soft bags to reduce the numbers of smashed glass vials received or to reduce storage space. Vials were still most commonly chosen due to cost and the flexibility to use any contrast media within an empty syringe. Mallinckrodt therefore contested that it would be difficult to persuade customers to purchase an expensive contrast media in a presentation which did not fulfil their requirements based on the alleged loan of an injector.

Mallinckrodt submitted that as outlined above, the Optivantage injector from Mallinckrodt was not limited solely to the use of pre-filled syringes. Customers could, and did, use empty syringes with contrast media from other suppliers. It did not make commercial sense to allegedly loan equipment based on an assumption that revenue would be achieved by the sale of contrast media if competitor contrast media could also be used.

Alleged practice

In its complaint, Bayer stated that it was 'aware that some NHS customers have confirmed that inducements are being offered'. If there was concrete evidence of this, Mallinckrodt urged the PMCPA to encourage Bayer to disclose to it names of hospitals for further investigation. Mallinckrodt would not expect any customer to have previously viewed a 'loan agreement' as an inducement to prescribe or to consider that Mallinckrodt had offered

an injector as a 'gift' rather than as part of a business deal which provided the means for administering their choice or presentation of contrast media. In addition, Mallinckrodt could supply contact details of customers who had had injectors on package deals to investigate whether they considered that Mallinckrodt had offered inducements.

Current practice

Package deals were developed based on customer usage requirements to ensure that the provision of an injector complied with Clause 18.1. Deals were not long term, they were mainly for 2-3 years. Provided the commitment to volume of Mallinckrodt product was achieved, customers could choose alternative contrast media suppliers whilst retaining the injector. Package deals were based on the value of the equipment being a given percentage of the total value of consumables/contrast media which was in accordance with NHS terms and conditions. The ownership of the injector was transferred to the customer on delivery as part of the total package deal and was inclusive of the purchase price of the pre-filled syringes. Mallinckrodt submitted that this was fair and reasonable as the equipment was necessary for performing clinical tasks as outlined in the supplementary information to Clause 18.1 Package Deals.

Mallinckrodt referred to its compliance calculator and package deal template which were used in executing the process since February 2015. The compliance calculator included installation costs, average selling price of the associated injector and service and maintenance costs in accordance with NHS terms and conditions.

Pricing for the NHS

Mallinckrodt submitted that the package deal stated list price, however, it did not sell injectors at list price. Since January 2012, it had operated on the basis that NHS supply chain pricing was visible to all and would therefore serve as its 'guide price' when quoting. NHS supply chain should be the most cost effective route to purchase a product and therefore its pricing must be in line or slightly above NHS supply chain end user pricing which typically included 5% on cost. This was in line with its average selling price. Mallinckrodt provided evidence that it had started to address the issue with a legal firm.

Tables provided showed that only one MR imaging injector had a price anywhere near the £20,000 quoted by Bayer. That injector had never been placed on a package deal with MRI contrast media since end users had made a clinical decision not to use Optimark (gadoversetamide), the Mallinckrodt MR imaging gadolinium contrast media. If the placement of injectors via any kind of deal was an inducement to prescribe rather than as a necessary component for the administration of the product choice, it would follow that Mallinckrodt would undertake these alleged activities in MR imaging as well.

Mallinckrodt provided a table of the NHS supply chain pricing as of January 2012 and January 2015.

Mallinckrodt submitted that market assumptions were not that injectors were sold for 'upward of £20,000' and it suggested that Bayer declared the average selling price of its injectors to the PMCPA to validate its comments and assist in benchmarking standards.

Conclusion

Mallinckrodt submitted that it had followed documented internal processes which recognised the Code as best practice and had already taken steps to rectify where it had fallen short of this as demonstrated by the evidence provided.

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The Panel decided that given Guerbet Laboratories Ltd's acquisition of Mallinckrodt on 27 November 2015 and in accordance with its established practice, Mallinckrodt was now covered by Guerbet's status as a non-member company which had agreed to comply with the Code and accept the jurisdiction of the Authority. The Panel would thus consider the complaint in the normal way. Mallinckrodt was invited to comment on this matter.

Further comments from Mallinckrodt

Mallinckrodt submitted that given the complaint was raised on 16 October 2015 in relation to activities prior to that date, it contested the Panel's decision that Mallinckrodt fell under the rules to comply with the Code and its associated jurisdiction during the period leading up to that date.

Mallinckrodt submitted that as outlined above, although it had not signed up as a non-member in the past, it had always sought to comply with the guidelines of the Code. Mallinckrodt noted that it was a separate legal entity in the UK with separate regulatory and marketing authorizations and associated premises.

Mallinckrodt had provided a detailed response regardless of its membership position in order to clarify the complaint process it had instated in the UK to ensure it met the guidelines of the Code.

Mallinckrodt submitted that its response pertained solely to the activities undertaken by it as a separate legal entity to its parent company Guerbet and to practices which occurred before the acquisition.

Mallinckrodt thanked the Panel for highlighting an inconsistency in its contract detail and confirmed that ownership of the injector was transferred to the customer upon delivery.

Mallinckrodt submitted that regrettably, there was no mechanism to recover the investment due to insufficient volume of product purchased by the customer. Volume commitment was typical practice in secondary care pharmaceutical tenders via purchasing consortia who had never offered the

mechanism to penalise customers for not achieving committed volumes. Through Mallinckrodt's knowledge of the radiology environment and close collaboration with customers, it was rare that a customer would over-commit except in exceptional circumstances such as unplanned down-time and this would be taken into consideration.

A contrasted scan was a necessary diagnostic procedure which was led purely by the number of scans required. Mallinckrodt could not therefore work with a customer to increase the number of scans performed to ensure that they achieved 5% threshold. Currently, Mallinckrodt did not want to impose a financial penalty on a customer for failing to use sufficient product.

Volumes for all customers were regularly monitored. A 'class A' sales operations and inventory planning process was based on building its manufacturing plan from customer level.

Mallinckrodt submitted that agreements were typically made for 2-3 years. The life of the injector was 7-10 years. To ensure greater compliance, the calculation was done based on the term of the package deal which was based on customer requirements. Mallinckrodt referred to its new compliance calculator and explained what the coloured cells represented. The time period was specified. Mallinckrodt welcomed suggestions from the PMCPA regarding how this could be improved.

PANEL RULING

The Panel noted Mallinckrodt's comment that its submission of a response was not an agreement to join the list of companies which, although non-members of the ABPI, agreed to comply with the Code and accept the jurisdiction of the Authority. The Panel noted that Mallinckrodt was a manufacturer and supplier of contrast media and injectors for diagnostic purposes. On 27 November 2015, Mallinckrodt CMDS (just injectors and contrast media) was transferred to Guerbet Laboratories under a share transfer. The Panel noted that Guerbet was a non-member company that had previously agreed to comply with the Code. When Mallinckrodt submitted its initial response to the PMCPA (8 January 2016) the companies had yet to be fully integrated. The Panel noted the company's submission that it had operated within the guidelines of the Code to the best of its ability since 2007. The Panel noted that the company's letterhead bore the prominent company name Guerbet in logo format beneath which in smaller typeface appeared 'Mallinckrodt UK Commercial Ltd, now part of Guerbet'. In the Panel's view given Mallinckrodt's acquisition by and ongoing integration with Guerbet it was covered by Guerbet's non-member status. Mallinckrodt had been so informed before the Panel's consideration of this matter and asked to comment.

The Panel also noted Mallinckrodt's submission that given the inter-company complaint from Bayer was made on 16 October 2015 in relation to activities before that date, it contested the decision by the Panel that the activity in question and the company fell under the Authority's jurisdiction. The Panel noted that the complaint dated 27 November was received by the Authority on 1 December. The Panel did not agree that the complaint solely related to matters prior to 16 October. In the Panel's view the broad allegation related to the principle of a package deal whereby an injector of a certain value was provided in conjunction with sales of contrast media. The purchasing organisation document was provided as an example. The document dated from September 2012 and the offers therein had according to Mallinckrodt recently been re-tendered. The Panel noted that the provision of package deals was an ongoing activity. The Panel considered that the activities in question at the date of complaint to the Authority came within its jurisdiction.

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 in breach, *inter alia*, of Clause 18.1.

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 such as 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 Mallinckrodt's submission that its injectors were not offered on long term or permanent loan. The Panel also noted the company's detailed submission about its past practices when it was part of a separate company at the time of the original purchasing organisation tender which referred to financial loan agreements. The Panel's understanding of Mallinckrodt's response was that post July 2013, when it became a separate company, these loan agreements were no longer offered. The Panel considered the complaint in relation to the company's account of its current practice which had been adopted since February 2015 and was thus in use at the date of the complaint and thereafter.

The Panel noted Mallinckrodt's explanation that package deals were developed based on customer usage requirements to ensure that the provision of an injector complied with Clause 18.1. Deals were mainly for 2-3 years. Provided the commitment to volume of Mallinckrodt product was achieved, customers were free to choose alternative contrast media suppliers whilst retaining the injector. Package deals were based on the value of the

equipment being a given percentage of the total value of consumables/contrast media which Mallinckrodt submitted was in accordance with NHS terms and conditions. The ownership of the injector was transferred to the customer on delivery as part of the total package deal and was inclusive of the purchase price of the pre-filled syringes. Mallinckrodt submitted that this was fair and reasonable due to the fact that the equipment was necessary for performing clinical tasks as outlined in the supplementary information to Clause 18.1.

Mallinckrodt referred to its compliance calculator which included installation costs, average selling price of the associated injector and service and maintenance costs which again Mallinckrodt submitted was in accordance with NHS terms and conditions. The Panel noted that the compliance calculator had been revised subsequent to the receipt of the present complaint; the Panel did not consider the revised version as part of this complaint.

The Panel noted that according to the template contract, in return for the payment of the equipment price, the service fee and the purchase of an agreed volume of consumables at agreed prices, Mallinckrodt agreed to supply equipment [the injector] and services to the customer. The customer acknowledged that the level of discount was offered on the basis of the total value of the package deal. The Panel noted that the template was inconsistent in some regards; it referred to title passing to the customer on payment in full of the equipment price although Mallinckrodt had confirmed that ownership passed on delivery. The Panel noted Mallinckrodt's submission that there was no contractual or other mechanism to recover the investment if insufficient volume was purchased and that currently the company did not wish to impose a financial penalty for failing to use sufficient product and not achieving the threshold. The Panel noted that Section 9 set out a termination clause by which either party could give notice for breach of a material term. The Panel noted that in effect under the contract the customer was paying for the injector at an agreed level of discount which was related to the total value of the package deal.

The Panel noted Mallinckrodt's submission that it had only one product, an MR imaging injector, with a price anywhere near the £20,000 quoted by Bayer. This injector had never been placed on a package deal with MRI contrast media since end users had made a clinical decision not to use the Mallinckrodt contrast media in question.

The Panel noted that the relevant supplementary information to Clause 18.1 referred to the provision of apparatus for administration. The Panel noted that the injector could be used not only with Mallinckrodt's contrast media but also with others. Ownership apparently passed to the customer upon delivery although the Panel noted its comments on the contract above. The injector would not be removed if agreed volumes were not achieved and it appeared that the total cost paid by the customer included an element which reflected the discounted cost of the injector. In the Panel's view the overall agreement did not appear to be unfair or unreasonable and thus it considered that the arrangements constituted a *bona fide* package deal.

The Panel noted that, as submitted by Mallinckrodt, 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 that the arrangements were a *bona fide* package deal and further that there was no benefit to an individual. In any event Mallinckrodt had not provided an injector which would sell for £20,000 to £35,000 as alleged. The Panel ruled no breach of Clause 18.1. Further, the Panel ruled no breach of Clause 2.

Complaint received **1 December 2015**

Case completed **4 May 2016**