ALCON LABORATORIES v ALLERGAN

Retrospective rebate scheme

Alcon alleged that a scheme whereby Allergan contractually granted NHS organisations retrospective cash rebates in relation to the prescription of the company's eye drops for glaucoma was an inducement to prescribe, recommend and buy Allergan's products. The scheme did not fall within the exclusion in the Code for measures and trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further, the scheme might subvert the ability of participating NHS organisations to form their own opinion of the therapeutic value of Allergan's glaucoma medicines; the scheme did not comply with high standards and it compromised the interests of glaucoma patients, and thus brought discredit upon, or at least reduced confidence in, the pharmaceutical industry.

The scheme granted cash rebates if the value of Lumigan, Ganfort and Combigan prescribed and dispensed within a defined geographic area met certain unit market thresholds, calculated as a percentage of the total market for glaucoma medicines. If a participating organisation achieved the lowest threshold then the lowest rebate rate would be paid. Two further, higher thresholds triggered the payment of higher rebate rates to a set maximum. The cash refund was paid into a separate fund managed by a fund management executive (typically three NHS employees) which governed spending of the fund. The stated intended purpose of the scheme was: '...to develop ophthalmic services in the community and or for the benefit of patients with ophthalmic conditions'. No payments to individuals were permitted (unless such payment went through the NHS payroll – for example, the fund could be used to employ a nurse).

Alcon was concerned that in its practical effect, the scheme unacceptably compromised prescribers' discretion to prescribe the most appropriate product for each patient.

Even in areas where the unit market share of Allergan's products was already around the lowest percentage required to trigger the scheme, prescribers would have to substantially increase the number of prescriptions for Allergan products (based on average market shares in the absence of any such scheme) in order to obtain the higher rebate rates which NHS organisations would naturally aim for.

The real issue was by how much Allergan's market share must increase in order to reach the required threshold to obtain the rebate ie, how many patients would be irrationally switched from a non-Allergan product to an Allergan product as a consequence of the scheme. The glaucoma market grew slowly (approximately 4% - 5% per year) with very few new entrants, and so the only way to increase market share was to decrease the share held by competing products by switching.

Allergan's attempt to dissociate itself from the potential negative effects of the scheme by arguing that whether any participating trust chose to adopt a strategy to maximise its rebate was outside of its control was disingenuous; it appeared that the scheme in itself incentivised participating trusts to adopt strategies to maximise their rebate which Alcon believed would inappropriately compromise clinicians' freedom to prescribe the most appropriate product to patients.

The risks associated with the scheme would be even more pronounced in certain areas where more than one organisation enrolled in the scheme would compete with others in the same area to meet the thresholds required to obtain the rebate. As an organisation would not know what threshold had been achieved by the other NHS organisation(s) in that area, it was likely to over-compensate by adopting strategies to significantly increase its own unit market share for Allergan products so that it was best placed to obtain the rebate itself.

Alcon gave a detailed account of its objections to the scheme which it considered sought to distort the market and incentivise NHS organisations to reach an unreasonable goal which might not benefit the NHS in the long-run.

Alcon considered that in seeking to attain the requisite thresholds for the grant of the rebate, NHS organisations might lose sight of the therapeutic value of Allergan's medicines such that they were prescribed irrationally, instead of as one possible product amongst an appropriate range of options.

Irrespective of whether the scheme was an inducement, Alcon considered that it did not maintain high standards because it promoted Allergan's products at the expense of good medical practice and incentivised NHS organisations to get rid of other glaucoma medicines, which compromised the interests of patients.

Alcon considered that irrespective of whether the scheme was an inducement to prescribe/recommend/buy Allergan's products it

brought discredit upon, or at the very least reduced confidence in, the pharmaceutical industry.

Alcon did not believe that the application of Clause 2 was avoided on the basis that the purpose of the scheme was to develop community ophthalmic services and/or benefit patients with ophthalmic conditions. Whilst there might be an overall benefit to ophthalmic patients generally, this might be at the expense of individuals who were denied the most appropriate product for their condition. Further, the scheme agreement specifically stated that: '... the fund management executive may decide to use the fund for purposes indirectly linked to ophthalmic patients or service development'. Therefore, it was not guaranteed that there would be any benefit at all to ophthalmic patients, let alone the glaucoma patients who were directly affected by the scheme.

The detailed response from Allergan is given below.

The Panel noted that Allergan described the scheme as a commercial agreement relating to discounts through rebates between Allergan and either a national health trust, NHS health board or an NHS practice based commissioning organisation. The retrospective rebate scheme agreement set out the terms of the rebate agreement, the accumulation of the rebate community fund and the use of the fund. According to the agreement the rebate was paid on the achievement of unit market share thresholds within the period of the agreement (12 months) applied to the value of a range of prescribed and dispensed Allergan ophthalmic medicines. The rebate was paid as a cash fund retrospectively on a quarterly or annual basis into the NHS organisation's business account. Before signing the agreement a fund management executive was appointed comprising three NHS employees. The agreement stated that the fund was intended to be used to develop community ophthalmic services and/or for the benefit of patients with ophthalmic conditions. However this was not an exclusive requirement – the fund management executive could decide to use the fund for purposes indirectly linked to ophthalmic patients or service development. Allergan would not influence or attempt to influence the use of the rebate fund. The agreement could only be cancelled early by mutual consent.

The powerpoint presentation 'B2B [business to business] Retrospective Discount Scheme' stated that to work within the Code the accrued cash fund would be treated as a separate trust-fund administered by a committee of stakeholders to manage and agree on the use of the fund which would be available to purchase products and services which would be recorded for audit. The Panel noted that the presentation was not wholly consistent with the agreement on this point.

The Panel noted that the Code excluded from the definition of promotion measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further the supplementary information to the Code stated that such measures or trade practices were excluded from the provision of that clause. Other trade practices were subject to the Code. The terms prices, margins and discounts were primarily financial terms.

The Panel noted that the Allergan scheme linked primary care prescribing volumes to a product where prescribing was usually initiated in secondary care. The agreement at issue covered both the cash rebate and the administration of the subsequent trust fund. The Panel considered that the establishment of a managed trust fund wherein cash accumulated was an integral part of the retrospective rebate scheme. Allergan had provided no evidence that such composite schemes were in regular use by the pharmaceutical industry prior to 1 January 1993. The Panel considered that such composite schemes could not take the benefit of the exemption. The scheme was thus subject to the Code.

The Panel noted that the agreement set out a loose framework for the establishment and operation of the rebate fund. According to the agreement Allergan would not influence or attempt to influence the use of the fund nor was it represented on the fund management executive. Fund managers would be given a monthly statement on the fund accrual. Monies would be paid quarterly or annually.

The Panel noted Alcon's allegation that the scheme operated as an inducement to prescribe Allergan's products contrary to the Code. The Panel noted the relationship between national unit share of Allergan's promoted portfolio, the market share in the majority of areas and/or NHS organisations and the threshold unit market share required to trigger the scheme. In that regard the Panel assumed that many areas would have to increase their prescribing of Allergan's products in order to reach the first threshold and thus qualify for a rebate. Four areas had signed up to the scheme of which two had unit shares above the first threshold, one above the second threshold and one just below the first threshold. The Panel considered that insofar as the scheme encouraged the trust to persuade prescribers to increase their prescribing so that the trust could gain a cash rebate, or increase its cash rebate, it could be interpreted as an inducement. The Panel noted that the Code related to inducements to individuals rather than organisations. The Panel considered that the scheme did not operate as an inducement to individuals nor was there evidence that payments had been made from a rebate fund to individuals as an inducement to prescribe or recommend Allergan's medicines contrary to the provisions of the Code. No breach was ruled

The Panel did not consider that the scheme was such that it made claims about the therapeutic

value of Allergan's medicines. In that regard the scheme was not such that it would prevent prescribers from forming their own opinion of the therapeutic value of the medicines. No breach of the Code was ruled.

The Panel noted the intended purpose of the rebate fund as set out in the Retrospective Rebate Scheme Agreement, namely to directly or indirectly develop ophthalmic services in the community and/or for the benefit of patients with ophthalmic conditions. The Panel considered that the rebate scheme in effect could be seen as a donation, grant or benefit in kind and should thus comply with the Code. The Panel noted that in the representatives' briefing document in a section entitled 'Actions to get started', step one involved the identification of hospitals with a market share above a stated percentage. The formulary status of all three glaucoma products in the hospital had to be determined and if one or more were not in the formulary immediate action was to be taken to gain formulary listings and also a special prices offer to the hospital pharmacy for all three glaucoma products must be made. Further, once the agreement had been signed the territory manager would support participating units with appropriate educational events and meetings. It thus appeared that a package of support was provided to the NHS organisation in addition to the cash rebate. The Panel considered that the provision of the cash rebate as a donation, grant or benefit in kind to the NHS organisation was inextricably linked to the promotion of Allergan's glaucoma medicines such that it amounted to an inducement to prescribe, supply, administer, recommend or buy such medicines contrary to the Code. A breach of the Code was ruled. High standards had not been maintained. A breach of the Code was ruled.

The Panel was concerned that the arrangements were such as to bring discredit upon or reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Upon appeal by Allergan the Appeal Board considered that although the scheme at issue contained elements of trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993, and which were otherwise exempt from the Code, the way in which the scheme operated as a whole meant that it had gone beyond that exemption and was thus subject to the Code.

The Appeal Board noted that the scheme was based upon a volume based percentage market share ie the amount of rebate due depended upon the number of bottles of Allergan products prescribed. The Appeal Board further noted that the representatives' briefing material stated that the territory managers would support participating units with appropriate educational events and meetings. Alcon confirmed at the appeal that it had no evidence to show that the provision of educational events and meetings was exclusively linked to the retrospective rebate scheme.

The Appeal Board considered the applicability of the Code and noted that in its view the rebates paid were a contractual financial arrangement. The amount paid was conditional on obtaining certain thresholds of market share. In that regard the Appeal Board did not consider that the rebate was a medical and educational good or service in the form of a donation, grant or benefit in kind. The Appeal Board thus ruled no breach of the Code.

The Appeal Board was concerned that the scheme could be perceived as an inducement to prescribe Allergan's products. The Appeal Board noted that generally such schemes might result in more prescriptions of a company's product. That was not necessarily unacceptable as long as the arrangements complied with the Code. The question to be established was whether the scheme amounted to an inappropriate inducement. A primary care organisation would potentially qualify for a larger cash rebate if its prescribers increased the number of packs of Allergan products they prescribed. Whilst it was true that one way to do this would be to switch from another company's medicines, nonetheless, the Appeal Board noted that there was no evidence of undue pressure on individual prescribers to do this. On the merits of this particular case the Appeal Board decided that Allergan had not failed to maintain high standards. No breach of the Code was ruled. The Appeal Board subsequently ruled no breach of Clause 2. The appeal was successful on all points.

Alcon Laboratories (UK) Limited complained about a retrospective rebate scheme operated by Allergan Ltd in relation to its medicines for glaucoma (Lumigan, Combigan and Ganfort). Inter-company dialogue had been unsuccessful.

COMPLAINT

Alcon noted that Allergan had contractual agreements with various NHS organisations, including primary care trusts (PCTs), such that they were granted retrospective cash rebates in relation to the prescription of Lumigan, Combigan and Ganfort (the 'scheme'). Alcon alleged that the scheme was an inducement to prescribe, recommend and buy Allergan's products contrary to Clause 18.1 of the Code and Regulation 21(1) of the Medicines (Advertising) Regulations 1994, or in the alternative Clause 18.5 of the Code. Alcon did not consider that the scheme fell within the exclusion for measures and trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further, the scheme contravened Clause 7.2 because it might subvert the ability of participating NHS organisations to form their own opinion of the therapeutic value of Allergan's glaucoma medicines; Clause 9.1 because the scheme did not

comply with high standards and Clause 2 because it compromised the interests of glaucoma patients, and thus brought discredit upon, or at least reduced confidence in, the pharmaceutical industry.

Alcon stated that Allergan had approached different ophthalmic departments in the UK, proposing that they signed up for the scheme. Alcon provided a copy of the Retrospective Rebate Scheme Agreement that it believed certain NHS organisations had signed, together with a copy of a slide presentation that it understood Allergan used to promote the scheme.

NHS organisations participating in the scheme were granted cash rebates if the value of Lumigan, Ganfort and Combigan prescribed and dispensed within a defined geographic area met certain unit market thresholds, calculated as a percentage of the total market for glaucoma medicines. For example, in order for an NHS organisation to obtain the lowest rebate rate then a pre-set percentage of all glaucoma prescriptions within a certain area must be for Allergan's products.

The rebate fund might be accessed on a quarterly or annual basis and the period of the agreement was one year. A fund management executive (typically three employees of the NHS) would have sole access to the fund and governed spending of the fund. No payments to individuals were permitted (unless such payment went through the NHS payroll – for example, the fund could be used to employ a nurse).

Alcon was concerned that in its practical effect, the scheme unacceptably compromised prescribers' discretion to prescribe the most appropriate product for each patient, and encouraged irrational switching. This was of particular concern in the context of glaucoma medicines because it was often arbitrary as to why a patient responded better to one than another with regards to efficacy and tolerance. It was therefore crucial that prescribers were not inappropriately fettered in their prescription choices.

According to Allergan, 'The thresholds [required for obtaining the rebate] are specifically set at a low level of unit share so that clinicians maintain the freedom to prescribe the most appropriate product for each patient'. Thus, it seemed that Allergan agreed that unless the market share thresholds were indeed set at an appropriately low level, clinicians' freedom to prescribe the most appropriate product for each patient would be compromised.

However, Allergan had not substantiated what it meant by a 'low level of unit share'. Alcon provided a table of data to show that a minimum threshold was set to trigger the scheme and as unit market share increased then so did rebate to a fixed maximum. Clearly, the unit market share required to trigger the payment of the rebate could only be low as relative to the unit market share in the absence of any such scheme. However, from the example set out in Allergan's slide presentation for one particular defined area which relied on figures between September 2007 and February 2008, it was clear that the unit market share for Allergan's products was well below the percentage required to trigger the scheme.

Alcon submitted that to obtain the lowest rebate, some NHS organisations would have to increase the number of prescriptions of Allergan products in order to meet the unit market share threshold. Even in areas where the unit market share was already around the threshold value for Allergan's products, prescribers would have to substantially increase the number of prescriptions for Allergan products (based on average market shares in the absence of any such scheme) in order to obtain the higher rebate rates which NHS organisations would naturally aim for.

In inter-company dialogue, Allergan had declined to state what level of unit share it considered to be low in terms of the difference between the unit market share required to obtain the rebate and the current market share held by Allergan in the areas concerned. Allergan had implied without adequate justification that it believed that the unit market share threshold was low, but Alcon was not satisfied that this was the case. Allergan's comment about the market share threshold and the number of other patients that could still be prescribed other products was misleading. The real issue was by how much Allergan's market share must increase in order to reach the required threshold to obtain the rebate - in other words, how many patients would be irrationally switched from a non-Allergan product to an Allergan product as a consequence of the scheme. The glaucoma market was subject to slow growth (approximately 4% - 5% per year) with very few new entrants, and so the only means of increasing market share was to decrease the share held by competing products by switching. Allergan's own example in its slide presentation indicated that the current unit share for its glaucoma products was well below the first threshold in certain areas. Further, Allergan referred only to the lowest threshold in an attempt to justify the scheme – but NHS organisations would naturally aim for the highest rebate rate which meant that Allergan's products would have to attain a greater market share in the area concerned. Alcon inferred from Allergan's silence on the issue that it did not adjust the unit market share thresholds under the agreement in order to ensure that they were realistic for each participating NHS organisation. For example, it seemed that the same unit market share threshold targets were imposed on each participating NHS organisation, irrespective of geographical differences in Allergan's market share in the absence of any such scheme.

Whilst the scheme was not primarily designed as a switch scheme, Alcon believed Allergan intended to encourage a switch from competitor products as this was the only way to increase its own market

share. Allergan's attempt to dissociate itself from the potential negative effects of the scheme by arguing that whether any participating trust chose to adopt a strategy to maximise its rebate was outside of its control was disingenuous; it appeared that the scheme in itself incentivised participating trusts to adopt strategies to maximise their rebate which Alcon believed would inappropriately compromise clinicians' freedom to prescribe the most appropriate product to patients.

Although Alcon understood that the scheme was structured such that, generally, there would be only one NHS organisation participating in a particular area, there would be cases where more than one was participating in the scheme in a particular area (eg London). The risks associated with the scheme would be even more pronounced in such cases as this would mean that the organisations would be competing with each other to meet the thresholds required to obtain the rebate. As a particular organisation would not be certain as to what threshold had been achieved by the other NHS organisation(s) in that area, it was likely to over-compensate by adopting strategies to significantly increase its own unit market share for Allergan products so that it was best placed to obtain the rebate itself.

Further, although the scheme agreement was for one year in all cases, participating NHS organisations might elect to receive fund payments on a quarterly or annual basis. Allergan's slide presentation explained that an annual payment would be larger than four quarterly payments as a consequence of exponential growth of the fund. NHS organisations would therefore be encouraged to accept annual payment. Even though Allergan would, in any event, provide quarterly reports showing unit market share, the consequence of accepting annual payment was that participating NHS organisations might be tempted to prescribe even more Allergan products than was necessary to obtain the rebate on the basis that the accounting period was longer, and there was therefore greater uncertainty. Accordingly, for those NHS organisations which elected for annual payment (which Alcon anticipated would be the majority), the effects of the scheme would be even more pronounced.

Finally, for the sake of completeness Alcon added that it did not understand the relevance of Allergan's comment that: '...hospitals are today...awarding single product tenders that remove prescriber choice very significantly and yet, provided the NHS believes several different products meet the same clinical need, this is not viewed as objectionable'.

A tender procedure, under which a range of products was assessed for clinical/cost effectiveness according to defined criteria, was very different to a unilateral approach by a pharmaceutical company which sought to incentivise NHS organisations to buy/recommend its products. Allergan also likened the scheme to a patient access/risk sharing scheme (many of which had been taken into account by the National Institute for Health and Clinical Excellence (NICE) in its assessments of cost effectiveness). However, the objective of the scheme was very different from that of a patient access scheme whereby the price paid for a medicine was fully or partially refunded if the outcome of the use of the medicine in a patient failed to meet certain criteria. In any case, Alcon understood that risk sharing/outcome guarantee schemes fell outside the scope of joint working and must be reviewed in accordance with the Code. Alcon maintained its arguments for a breach of the Code.

Breach of Clause 18 – inducement to prescribe

The scheme operated in such a way that each prescription of a non-Allergan product was a potential obstacle to obtaining the rebate. Therefore, participating NHS organisations would be induced to buy Allergan products, more or less to the exclusion of other glaucoma medicines. Further, the prescriber might be induced to prescribe only Allergan's products to new patients, and to switch patients who were on other products to an Allergan product. Alcon believed that this inducement would be achieved by way of changes to the formularies such that other manufacturers' products would be excluded or removed in favour of Allergan's products in order that PCTs maximised their rebate. Effectively, therefore, the scheme also induced PCTs to recommend Allergan products. Whilst the formulary would state in effect that the prescribing choice was ultimately subject to the health professional's discretion, the scheme would encourage the PCT to pressurise health professionals to prescribe Allergan's products as a first line treatment as a matter of course, thus ultimately infringing prescribers' rights to freely prescribe the medicine they considered most benefited the patient.

Clause 18.1

Alcon alleged that the scheme was in breach of Clause 18.1.

Alcon recognised that the scheme was not a conventional inducement to prescribe under Clause 18.1 because the inducement (the cash rebate) was not given directly to individual health professionals but rather to the NHS organisation. In this context, Alcon knew about the Code of Practice Appeal Board's ruling in Case AUTH/2095/2/08; Actelion v Encysive which Allergan had cited in inter-company dialogue.

However, Alcon did not believe that such a narrow construction should be given to Clause 18.1 considering that the scheme clearly did not comply with the principles of Clause 18, as revised in 2008. Indeed, Alcon noted that the scope of Clause 18 was significantly widened in 2008 when Clauses 18.5 and 18.6 were added, neither of which was limited to inducements to individual health professionals.

Alcon therefore understood that it was the clear intention of the 2008 Code to extend the restrictions on pharmaceutical companies in terms of offering inducements to prescribe, supply, administer, recommend, buy or sell any medicine in order to catch inducements in all contexts. Novel arrangements such as the one at issue - whereby a rebate was granted when a certain market share (expressed as a proportion of the total market) was attained - were perhaps not envisaged when Clause 18 was revised in 2008. Nevertheless, the scheme clearly violated the spirit of Clause 18. Alcon therefore maintained that the scheme breached Clause 18.1, as read in the light of Clauses 18.5 and 18.6.

Further, although the scheme did not allow direct payments to individual health professionals or to administrative staff, individuals might nonetheless benefit under the scheme because the rebate fund would be used at the discretion of the fund management executive.

Exemption to Clause 18.1

Allergan believed that the scheme was a legitimate form of volume based discount and that it therefore fell within the exemption to Clause 18.1. Whilst Allergan was correct that the offer of discounts on the supply of medicines was a well established and acceptable practice within the pharmaceutical industry, the scheme was evidently a novel form of discount arrangement because it was based on market share and thus depended on other products disappearing from the market. Allergan attempted to justify the fact that unit market share was the operative trigger for the rebate on the basis that this: '... enable[s] Primary Care Trusts and hospital trusts which serve the needs of smaller relevant patient populations to qualify for discounts even though the absolute volumes of glaucoma products prescribed for the patients for whom they are responsible may be smaller than some others'.

Allergan seemed to imply that structuring the scheme on the basis of unit market share targets was the only way that PCTs and hospital trusts which served the needs of smaller patient populations could benefit from a favourable price arrangement. However, such NHS organisations would alternatively benefit from a standard volume based discount (eg buy x amount and get y amount free), provided that x was based on a realistic purchasing target. Alcon's concern about the scheme was that the unit market share thresholds set would, *de facto*, compromise clinicians' freedom to prescribe the most appropriate product to patients and encourage irrational switching. Further, Alcon disagreed with Allergan's suggestion that the same risk of irrational prescribing might be said to arise with any volume discount arrangement. In contrast with the scheme, standard volume discount arrangements were not structured in such a way that there was the necessary effect of removing other products from the market. Moreover, the rebate did not provide a discount to the payer (the NHS) – rather, it was in the form of a fund which might be applied at the discretion of the fund managers. Alcon considered that the distinction between an arrangement which offered a discount to the payer and one which did not was an important one. This was illustrated in Case AUTH/691/4/98; Pasteur Mérieux MSD v Wyeth where Wyeth was ruled in breach of Clause 18.1 (as it then was) for offering practices which purchased its influenza vaccine a sum of money to be used for training. The Panel explained why there was a distinction between offering a standard discount vs a collateral benefit associated with the sale of medicines: 'The Panel accepted that observers might consider the position to be illogical in that the provision of a percentage of sales value in the form of a training grant was unacceptable under the Code whereas the allowance of an extra discount would not have been unacceptable. This was, however, the result of the exemption of discounts from the provisions relating to gifts, a situation which arose from the fact that the Code followed both UK and European law in this respect'. Although Clause 18 had since been revised, the case usefully illustrated why the arrangement at issue was not a standard volume based discount.

Alcon therefore disagreed with Allergan's assertion that the scheme was exempted from Clause 18.1 on the basis that it was a discount scheme. Indeed, the supplementary information to Clause 18.1 stated 'Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 are outside the scope of the Code...Other trade practices are subject to the Code'.

Allergan had provided no evidence that an arrangement such as the one at stake was in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 and indeed, Alcon did not accept that this was the case. On the contrary, it should be noted that the Executive Summary attached to Allergan's agreement, stated in the first section that 'The Department of Health and ABPI changed the rules on the nature of commercial relationships between organisations of the NHS and the pharmaceutical industry in 2008 enabling new and innovative approaches to contracting with organisations of the NHS' [emphasis added].

Thus, Allergan itself characterised its scheme as a novel form of arrangement, which lent further support to Alcon's contention that such an arrangement was not in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. For the sake of completeness, Alcon added that it appeared from the above statement as well as inter-company dialogue that Allergan believed that the scheme fell within legitimate joint working arrangements with the NHS. However, Alcon disputed this because one of the essential features of a joint working arrangement was that there was a pooling of resources, which the scheme lacked.

Accordingly, Alcon considered that the scheme was an inducement to prescribe Allergan's products in breach of Clause 18.1.

Clause 18.5

Alcon considered that there were two ways of looking at the scheme: either it was caught by Clause 18.1 or by Clause 18.5.

As explained above, the rebate did not provide a discount to the payer (ie, the NHS), which was a matter of concern to Alcon (and an indication that the rebate offered under the scheme was not a standard volume based discount), as explained above. Rather, the scheme provided a collateral benefit associated with the prescription of Allergan's glaucoma medicines (provided these met the requisite threshold) in the form of a cash fund that was apparently intended: '...to develop ophthalmic services in the community and or for the benefit of patients with ophthalmic conditions. However this is not an exclusive requirements - the fund management executive may decide to use the fund for purposes indirectly linked to ophthalmic patients or service development'.

Therefore, under Clause 18.5, the rebate might be seen as a kind of grant ostensibly intended for the provision of medical services. However, grants were only permitted under Clause 18.5 if they did not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Alcon believed that the scheme induced the contracting NHS organisation to buy and recommend Allergan's glaucoma products, and the prescribers to prescribe them.

Alcon therefore alleged that the scheme was in breach of Clause 18.1, or in the alternative Clause 18.5. Alcon noted that the Authority's guidance on 'Joint working and the ABPI Code of Practice for the Pharmaceutical Industry' stated that although Clause 18.5 did not generally relate to activities involving the sale of medicines, it might apply 'if the company's medicines were not sold as part of the joint working'. As Alcon explained above, it believed that joint working had no application to the scheme and that Clause 18.5 was therefore relevant in this context.

Breach of Clause 7.2 – ability to form an opinion on the therapeutic value of the medicine

Alcon was concerned that the scheme was presented to NHS organisations in such a way that they were unable to form their own opinion of the therapeutic value of the medicine, irrespective of whether the arrangement was held to constitute an inducement for the purposes of Clause 18.

On the basis of inter-company correspondence as well as the slide presentation that Alcon understood Allergan used to promote the scheme, Alcon was not confident that NHS participating organisations were told that whilst increasing market share allowed hospitals to qualify for a cash rebate, additional costs would occur in the community where other glaucoma medicines offered cost effective alternatives (for example, compare Alcon's product Travatan at £10.17 vs Allergan's product Lumigan at £10.30).

Further, as a general point, Alcon considered that as a whole the scheme sought to distort the reality of the market (where there was an appropriate range of products to meet the individual needs of different patients), and incentivised NHS organisations to sign up to a scheme which imposed an unreasonable goal and which might not benefit the NHS in the long-run.

Alcon therefore considered that in seeking to attain the requisite thresholds for the grant of the rebate, NHS organisations might lose sight of the therapeutic value of Allergan's medicines such that they were prescribed irrationally, instead of as one possible product amongst an appropriate range of options.

Breach of Clause 9.1 – maintenance of high standards

Clause 9.1 provided that high standards must be maintained at all times.

Irrespective of whether the scheme was an inducement within the meaning of Clause 18, Alcon considered that it did not maintain high standards because it promoted Allergan's products at the expense of good medical practice (as explained above) and incentivised NHS organisations to get rid of other glaucoma medicines, which compromised the interests of patients.

Breach of Clause 2 – bringing discredit upon/reducing confidence in the pharmaceutical industry

Alcon noted that rulings of a breach of Clause 2 were reserved for cases of particular censure. It considered that this case warranted such censure and that irrespective of whether the scheme was an inducement to prescribe/recommend/buy Allergan's products (which Alcon strongly believed it was), it brought discredit upon, or at the very least reduced confidence in, the pharmaceutical industry. This was because Allergan effectively used the scheme to encourage NHS organisations to get rid of competing products, with the consequence that patients might not be prescribed the most appropriate product for them. The scheme was therefore detrimental to the interests of patients who would be victim to an unnecessary and inappropriate fettering of prescribers' discretion.

For the sake of completeness, Alcon did not believe that the application of Clause 2 was avoided on the basis that the stated intended purpose of the scheme was: '...to develop ophthalmic services in the community and or for the benefit of patients with ophthalmic conditions'. Whilst there might be

an overall benefit to ophthalmic patients as a general class, this might be at the expense of individuals who were denied the most appropriate product for their condition. Further, the scheme agreement specifically stated that: '... the fund management executive may decide to use the fund for purposes indirectly linked to ophthalmic patients or service development'. Therefore, it was certainly not guaranteed that there would be any benefit at all to ophthalmic patients, let alone the glaucoma patients who were directly affected by the scheme.

RESPONSE

By way of background Allergan provided copies of the scheme agreement, an executive summary, a powerpoint presentation and an internal briefing document. There were no other documents relating to the scheme. Allergan believed the scheme was a legitimate form of volume based discount and as such complied with Clause 18.1 of the Code and the UK Advertising Regulations. Allergan understood that the Authority accepted that discounts fell outside Regulation 21(1) of the Advertising Regulations because they were covered by the exemption in Regulation 21(4) and that such discounts might legitimately include financial rebates, providing these were transparently agreed and invoiced. A rebate was merely a financial term and a means of accounting for a quantity discount that was calculated over more than one account period and invoice.

The scheme was not a novel arrangement, it was a volume based discount, transparently agreed and invoiced. Therefore, the exemption provided by Clause 18.1 and Regulation 21(4) applied. The scheme and associated documentation was examined in this context, as a scheme that fell outside of the Code.

Overview of the scheme

The scheme was a commercial agreement relating to discounts through rebates between Allergan and either a national health trust, NHS health board or an NHS practice based commissioning organisation.

In outline, a retrospective rebate would be applied to the value of a range of Allergan ophthalmic medicines prescribed and dispensed within a defined geographic area for a defined period of time. The rebate would be paid on achievement of unit market share thresholds within the period of the agreement. The rebate was the percentage of the unit cash value (number of units of medicine prescribed multiplied by the NHS tariff price) at NHS tariff prices for the named Allergan glaucoma medicines issued to patients via a GP's prescription (FP10). Allergan products purchased by NHS secondary care trusts (from Allergan directly or via pharmaceutical wholesalers) were excluded from the agreement.

The use of unit (volume-based) market share thresholds as opposed to value based market share thresholds was important. Market share distorted the market position in Allergan's favour making its products appear to be more frequently used than they were, it measured relative value whereas unit share was absolute volume.

Unit share removed price from the equation giving all the products in the market a value of one. This meant that a doctor knew that a 17% unit share meant that 17 of every 100 patients were using that product. Market share measured the value of a market position in cash terms. Market share was the proportion in cash value of a given product in a market sector as measured by the cash worth of that market. This was a subtlety that distorted the market somewhat, as a lower volume product with a higher price would appear to most clinicians to be a relatively more frequent choice of product. As a simplistic example, if an established market comprised products at £2 per item and a new product entered the market at £20 per item then it would appear to be a popular choice in terms of market share because every one of the new medicines prescribed in market share terms was worth ten times the established market products.

Price	Volume	Value	Total Market	Unit Share	Market Share
£2	500	£1,000		83%	33%
£20	100	£2,000		17%	67%
			£3,000	100%	100%

Using unit share as the metric for the rebate scheme meant that when a doctor prescribed an Allergan product for a patient it counted as one, not as a proportion of the cash value of the market sector; it was easier for the clinician and authorities to understand and to keep in context. It also meant that all Allergan promoted glaucoma products counted equally. The importance of this was explained below.

The rebate was paid retrospectively as a cash fund into the business account of the NHS organization named in the agreement. The rebate was recorded through invoicing and was entirely transparent.

Before signing the agreement a fund management executive was appointed, typically three NHS employees, for example a pharmaceutical advisor, a medicines management or professional executive committee (PEC) lead, and an ophthalmologist or representative from the ophthalmic department.

Allergan broadly understood that the fund would be used to develop ophthalmic services in the community and/or for the benefit of patients with ophthalmic conditions. However, this was not a requirement – the fund management executive might decide to use the fund for purposes indirectly linked to ophthalmic patients or service development. The rebate fund would be used at the discretion of the fund management executive. Allergan had no influence over the use of the rebate fund. Indeed, the rebate could be put back into the

trust's medicine budget or paid into its capital expenditure account if so desired by the fund management executive.

Details of the scheme as requested by the Authority

Allergan submitted that the initial threshold was attainable for most areas which had its products on the formulary.

The Allergan noted its national unit share of its promoted portfolio in glaucoma. This was an average unit share, made up of the jigsaw of NHS organisations with differing influences and different decision makers. There was a normal distribution curve with outliers at either end. The majority of areas had a share close to the national and a significant volume of organizations were within 2% of the first threshold to trigger the scheme.

Currently, four areas had signed up to the scheme. Two entered with unit share above the first threshold, one with unit share above the second threshold and one was just below the first threshold. Approximately 36 others were considering the scheme and by the time they joined the scheme they would have achieved or be very close to the first threshold.

Overall, more than one in five NHS organisations had a unit share at or above the first threshold needed to trigger the scheme. However, there was massive variation in size between these organisations as it included the Scottish health boards and English PCTs.

Regarding the rebates paid to date, of the four areas currently signed up, three would be paid annually and one would be paid quarterly. Allergan had limited data, but the largest rebate, for the quarterly account, was projected to be no more than £1,200.

Regarding communication of the scheme to prescribers and NHS managers, as per the briefing document provided (UK/0046a/2008) the territory manager or area manager would contact the NHS business manager regarding a potential hospital that might be suitable for the scheme. The NHS manager would meet the lead clinician and PCT representative and present the scheme using the powerpoint presentation and document provided (UK/0046/2008). There was no additional documentation.

There was no communication with prescribers other than with those who formed part of the team assessing and, if appropriate, signing the agreement.

No Allergan employees were bonused according to take up of the scheme.

Response to specific allegations from Alcon

Alcon alleged that the scheme was a novel arrangement and operated as an inducement to prescribe, buy and recommend Allergan products. Allergan strongly disagreed.

Classification of the scheme as a standard volume based discount

As explained above, the rebate offered to NHS customers was calculated on the basis of unit market share. Customers, therefore, received a discount related to the volume of their orders; the higher the volume of orders the higher the discount. The total market share was relatively stable. In consequence, expressing the thresholds by reference to volume market shares was equivalent to expressing them in absolute volumes. Unit market share was chosen as the operative trigger to enable PCTs and hospital trusts, which served the needs of smaller relevant patient populations, to qualify for discounts even though the absolute volumes of products prescribed might be small. The scheme was, nevertheless, a volume based discount.

Allergan's experience of volume based discounts in the pharmaceutical industry was substantiated and pre-dated 1 January 1993. Allergan provided a list of such schemes as supporting evidence.

There was ample evidence of volume related retrospective rebate schemes in common use pre-1993, and in current practice from a number of named pharmaceutical companies. Indeed, Allergan understood that Alcon had recently offered volume related discounts to dispensing GPs and independent service providers. These agreements tended to be between pharmaceutical companies and dispensing GPs or pharmaceutical companies and NHS organisations such as buying groups or hospitals.

Allergan submitted that its scheme fell squarely within the parameters set out in the supplementary information to Clause 18.1 and the additional guidance provided by the MHRA in the Blue Guide 2005. It was a business to business discount scheme which was transparently agreed and invoiced and was of a type which was in regular use by a significant proportion of pharmaceutical industry before 1 January 1993. It was clear from the Blue Guide that, in order to benefit from the exemption, schemes did not have to be identical in every respect to schemes in use before 1993. The Blue Guide described by way of example of exempt schemes 'volume based discounts and similar offers' provided they were clearly identifiable and invoiced. Alcon's scheme did not, therefore, fall within the scope of the Advertising Regulations or the Code since there was nothing in the Code to suggest that the interpretation of exempt schemes should be narrower than that given in the Advertising Regulations. The Code required a higher burden of proof in that it required evidence that such schemes were in use by a significant proportion of the pharmaceutical industry before 1 January 1993, as opposed to merely being in existence before that date but Allergan considered

that this burden was fully discharged in any event by the examples given in the Blue Guide itself and as above.

As noted by Alcon, one bullet point in the general background document entitled 'Executive Summary for the Retrospective Rebate Initiative' mentioned changes in 2008 regarding joint working arrangements. However, Allergan submitted that it had never claimed its scheme was a joint working arrangement either to Alcon or with Allergan's customers. This bullet point was given for context alongside information on fast moving consumer goods/manufacturing industry retrospective discounts and general retrospective volume based discount schemes.

Clause 18

Even if the scheme was not exempt, there was no breach of Clause 18.1 as payments were made to institutions rather than to individuals. The Appeal Board ruling in Case AUTH/2095/2/08 was conclusive authority for this proposition. The 2008 amendments to the Code did not undermine the precedent set by this ruling.

Alcon had also alleged that the scheme breached Clause 18.5 which dealt with the provision of medical and educational goods and services in the form of donations, grants and benefits in kind. The scheme did not involve the provision of grants, donations or benefits in kind. It was a transparently agreed and invoiced business to business discount. Neither Directive 2001/83/EC, which was the legal basis for the 1994 Advertising Regulations, nor the Code was designed to prevent pharmaceutical companies competing for customers on price. Such a conclusion, which seemed to underlie Alcon's objections to the scheme, would be quite perverse and certainly illegal under European Community competition rules.

Clause 7.2

The alleged breach of Clause 7.2 was puzzling. Clinicians would have used a range of materials and documents to form their own opinion of the therapeutic value of a medicine. The hospital drugs and therapeutics committee would have decided to add the Allergan products to the formulary before any consideration of participating in the retrospective rebate scheme.

At a very basic level a prescriber would not use the retrospective rebate materials to help form their opinion regarding the therapeutic value of a medicine or medicines.

With regard to the rather tenuous allegation that an organisation (rather than an individual prescriber) would lose sight of the therapeutic value of Allergan's medicines, there was no evidence that any NHS organisation had been misled into joining the scheme against its better interests or those of its patients. Allergan took care that the documents setting up the scheme were signed by a person with authority to bind the contracting NHS organisation, with current signatories including a clinical director, director of pharmacy (x2) and a head of procurement. The fund into which the rebate was paid was administered by three senior appointees of the NHS organisation. Allergan had no influence on these appointments nor as to how the NHS organisation used the rebate.

It was simply not a feature of the scheme that it could lead to irrational prescribing. Doctors were required, by their professional code of ethics and, where they were GPs in contract with a PCT, by the terms of their contract, to take account of the best use of resources. This meant that where there was more than one equally suitable product the prescriber should prescribe the product which provided the best value. This did not necessarily mean the product which had the lowest acquisition cost. The value of rebates should also form part of that judgment. This much was evidenced by the numerous patient access schemes which had been approved by the Department of Health (DoH) in recent years and had been taken into account by NICE in its assessments of cost effectiveness.

The risk of 'irrational prescribing' (that might be said to arise with any volume discount arrangement) was not only avoided by the guidance to which Allergan had referred above, but also by the fact that the lowest rebate rate was 16% which meant, of course, that a rebate was due if 16 out of 100 patients got one of the three relevant Allergan products. None of those 16 Allergan products would be prescribed unless the prescriber considered that the product was suitable for the patient. The fact that another product might also be suitable but offered less value to the purchasing primary care organisation was quite properly a relevant factor to be taken into account by the prescriber in reaching his or her ultimate decision. The corollary was that 84 other patients could still be prescribed other products. The suggestion that such a scheme curtailed clinical freedom was without foundation and sat uncomfortably with the fact that hospitals awarded single product tenders that left prescribers with no choice at all, and yet, provided the NHS believed several different products met the same clinical need, this was not viewed as objectionable. Allergan did not consider it could be suggested that patient access schemes, to which its rebate scheme could be likened, were anything but beneficial to the NHS and to patients.

Clauses 9.1 and 2

Allergan submitted that the rebate scheme did not promote its glaucoma products at the expense of good medical practice. The interests of patients and participating NHS organisations were promoted by the scheme, in that glaucoma medicines, which prescribers had professionally judged suitable for their patients, were provided at excellent value. Such a scheme did not discredit or reduce confidence in the pharmaceutical industry. In

Allergan's view the scheme represented good practice in the pharmaceutical industry of a type which was encouraged by the DoH, NICE and by the ABPI itself, as evidenced by the terms of the 2009 Pharmaceutical Price Regulation Scheme.

Allergan noted that the pack of materials from the Authority included an Alcon briefing document entitled 'Allergan Rebate/Reimbursement Scheme'. Allergan believed it might have received this in error and noted that this document had not been part of this ongoing complaint, and that this was the first time it had seen this document. It contained unsubstantiated allegations and many inaccuracies about Allergan's scheme and its implementation. Allergan was concerned by the tone and content of this document and asked that it was not considered by the Authority as part of the complaint.

Competition law issues

As would be clear from the correspondence provided, far from being prejudiced by Allergan's reasonable refusal to disclose competitively-sensitive information to it, Alcon appeared to have had a copy of the scheme and supporting documentation since the start of inter-company dialogue. In response to Alcon's repeated requests for the disclosure of these competitively-sensitive documents, Allergan had always made clear that it was unwilling to disclose them because of its obligations under competition law. As the two companies were competitors, and given that the agreement contained competitively sensitive data concerning prices, Allergan had declined to share a copy of the scheme agreement. Allergan was concerned that Alcon had acquired this level of confidential and competitively-sensitive information.

* * * * *

The Panel noted Allergan's request that the Alcon internal document entitled 'Allergan Rebate/Reimbursement Scheme' should not be considered by the Panel. That the document was not disclosed during inter-company dialogue would not prevent Alcon from submitting it to support the complaint. The document referred to matters which had been the subject of inter-company dialogue. It was for the Panel to decide what weight to attach to the document.

* * * * *

PANEL RULING

The Panel noted that its concern was to consider the allegations in relation to the Code and not the MHRA Blue Guide or UK law.

The Panel noted that Allergan described the scheme as a commercial agreement relating to discounts through rebates between Allergan and either a national health trust, NHS health board or an NHS practice based commissioning organisation. The retrospective rebate scheme agreement set out the terms of the rebate agreement, the accumulation of the rebate community fund and the use of the fund. According to the agreement the rebate was paid on the achievement of unit market share thresholds within the period of the agreement (12 months) applied to the value of a range of prescribed and dispensed Allergan ophthalmic medicines. The rebate was paid as a cash fund retrospectively on a quarterly or annual basis into the NHS organisation's business account. Before signing the agreement a fund management executive was appointed comprising three NHS employees eg a pharmaceutical advisor, a medicines management or PEC lead and an ophthalmologist/representative from the ophthalmic department. The agreement stated that the fund was intended to be used to develop community ophthalmic services and/or for the benefit of patients with ophthalmic conditions. However this was not an exclusive requirement – the fund management executive could decide to use the fund for purposes indirectly linked to ophthalmic patients or service development. Allergan would not influence or attempt to influence the use of the rebate fund. The agreement could only be cancelled early by mutual consent.

An executive summary set out the background to rebate schemes noting that the DoH and the ABPI changed the rules on the nature of commercial relationships between NHS organisations and the pharmaceutical industry in 2008 enabling new and innovative approaches to contracting. It stated that the rebate fund provided much needed cash liquidity to organisations rich in notional cash such as prescribing budgets. The executive summary differed from the agreement in its description of the governance of the rebate funding; it stated that no payments could be made to individuals other than cash payments to certain individuals through the NHS payroll. The agreement however was silent on this point.

The powerpoint presentation 'B2B [business to business] Retrospective Discount Scheme' stated that to work within the Code the accrued cash fund would be treated as a separate trust-fund administered by a committee of stakeholders to manage and agree on the use of the fund which would be available to purchase products and services which would be recorded for audit. The Panel noted that the presentation was not wholly consistent with the agreement on this point.

The Panel noted that Clause 1.2 excluded from the definition of promotion measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further the supplementary information to Clause 18.1 stated that such measures or trade practices were excluded from the provision of that clause. Other trade practices were subject to the Code. The terms prices, margins and discounts were primarily financial terms.

The Panel noted that Allergan had provided brief details of schemes run by six companies which it argued either previously or currently provided volume based discounts to dispensing GPs and others. The Panel considered, however, that there was an important difference between a cash rebate and a discount. Only two of the schemes detailed by Allergan referred to rebates; the precise details of the schemes were unknown. The Panel noted that the Allergan scheme linked primary care prescribing volumes to a product where prescribing was usually initiated in secondary care. The agreement at issue covered both the cash rebate and the administration of the subsequent trust fund. The Panel considered that the establishment of a managed trust fund wherein cash accumulated was an integral part of the retrospective rebate scheme. Allergan had provided no evidence that such composite schemes were in regular use by the pharmaceutical industry prior to 1 January 1993. The Panel considered that such composite schemes could not take the benefit of the exemption. The scheme was thus subject to the Code.

The Panel noted that the agreement set out a loose framework for the establishment and operation of the rebate fund. According to the agreement Allergan would not influence or attempt to influence the use of the fund nor was it represented on the fund management executive. Fund managers would be given a monthly statement on the fund accrual. Monies would be paid quarterly or annually.

The Panel noted Alcon's allegation that the scheme operated as an inducement to prescribe Allergan's products contrary to Clause 18.1. From the market details provided by Allergan the Panel assumed that many areas would have to increase their prescribing of Allergan's products in order to reach the first threshold and thus qualify for a rebate. Four areas had signed up to the scheme of which two had unit shares above the first threshold, one above the second threshold and the other just below the first threshold. The Panel considered that insofar as the scheme encouraged the trust to persuade prescribers to increase their prescribing so that the trust could gain a cash rebate, or increase its cash rebate, it could be interpreted as an inducement. The Panel noted that Clause 18.1 related to inducements to individuals rather than organisations. The Panel considered that the scheme did not operate as an inducement to individuals nor was there evidence that payments had been made from a rebate fund to individuals as an inducement to prescribe or recommend Allergan's medicines contrary to the provisions of Clause 18.1. No breach of that clause was ruled

The Panel noted the intended purpose of the rebate fund as set out in the Retrospective Rebate Scheme Agreement, namely to directly or indirectly develop ophthalmic services in the community and/or for the benefit of patients with ophthalmic conditions. The Panel considered that the rebate scheme in effect could be seen as a donation, grant or benefit in kind and should thus comply with Clause 18.5.

The Panel noted that in the representatives' briefing document in a section entitled 'Actions to get started', step one involved the identification of hospitals with a market share above a stated percentage. The formulary status of all three glaucoma products in the hospital had to be determined and if one or more were not in the formulary immediate action was to be taken to gain formulary listings and also a special prices offer to the hospital pharmacy for all three glaucoma products must be made. Further, once the agreement had been signed the territory manager would support participating units with appropriate educational events and meetings. It thus appeared that a package of support was provided to the NHS organisation in addition to the cash rebate. The Panel considered that the provision of the cash rebate as a donation, grant or benefit in kind to the NHS organisation was inextricably linked to the promotion of Allergan's glaucoma medicines such that it amounted to an inducement to prescribe, supply, administer, recommend or buy such medicines contrary to Clause 18.5. A breach of that clause was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel did not consider that the scheme was such that it made claims about the therapeutic value of Allergan's medicines. In that regard the scheme was not such that it would prevent prescribers from forming their own opinion of the therapeutic value of the medicines. No breach of Clause 7.2 was ruled.

The Panel was concerned that the arrangements were such as to bring discredit upon or reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL BY ALLERGAN

Allergan stated that the following were the essential elements for the retrospective rebate scheme:

- The scheme related to the sales of Allergan's products for glaucoma. There was a range of products available to ophthalmologists with which to treat their glaucoma patients. Allergan had a minor share in this market. In many cases, several products, including, Allergan's, would be equally suitable for treating a particular patient.
- The prescription of products for glaucoma was initiated by ophthalmic specialists in secondary care. Repeat prescriptions were often provided in primary care but there was little or no opportunity for a GP to initiate or change a patient's medicine, as he or she was seldom qualified to make that decision.
- Ophthalmic services in primary care were commissioned by primary care trusts and commissioning organisations, who were active participants in the design of those services.
- The scheme was promoted to primary care trusts, hospital trusts, NHS practice based commissioning organisations and NHS health boards. It was not promoted to individual prescribers.

- The scheme offered a cash rebate to participating organisations payable if FP10 prescriptions of Allergan's glaucoma products in a relevant geographical primary care area exceeded certain volume based thresholds. The maximum cash rebate rate was capped at a set percentage.
- The thresholds were expressed as a percentage of unit (rather than value) market share in order not to discriminate against organisations serving small geographical areas or ones with a sparse population.
- The first threshold was set to reflect the range of existing observed prescribing levels across a range of trusts.
- No NHS organisation was required to agree to prescribe Allergan's products in order to take part in the scheme. Allergan's products needed only to be available as an option for ophthalmic specialists to prescribe if they judged them to be suitable for any particular patient.
- Any NHS organisation wishing to take part in the scheme had to sign an agreement in which the arrangements for the cash rebate were described. The signatory was in all cases a senior manager with authority to enter into agreements on behalf of the trust.
- The fund into which the cash rebate was paid was maintained in the business account of the participating NHS organisation and administered by three senior employees, for example, a pharmaceutical adviser, an ophthalmologist, a medicines manager or, in the case of primary care organisations, a professional executive committee lead.
- The fund administrators decided how to use the rebate.
- Allergan had no influence and, in most cases, no knowledge of how the funds were used. The funds would in all cases benefit the NHS, however, in the absence of undetected fraud by the fund administrators. There was no suggestion in the complaint or in the ruling that the funds had been used for anything other than the benefit of NHS patients.
- NHS organisations signing up to the scheme might be additionally offered educational activities but the provision of these services was not linked to any level of prescriptions for Allergan products or any prescriptions at all. The provision of educational services was not linked to any claim for a rebate on purchases.

Allergan submitted that the scheme was exempt from the scope of the Code and that, even if it was not found to be exempt from the scope of the Code, it did not breach Clause 18.5. The retrospective rebate scheme was an example of a measure or trade practice relating to prices, margins and discounts in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Such activities were outside the scope of the Code, as provided for in Clause 1.2.

Allergan submitted that this exclusion derived from that fact that the provisions of the Code to a significant extent reflected the legal framework regulating pharmaceutical advertising provided for by Article VIIIa of Directive 2001/83/EC (the 'Directive'). Recital (50) to the Directive provided that 'persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements'. This aim found legislative form in Article 94 of the Directive which prohibited the offer of '... gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply them unless they are inexpensive and relevant to the practice of medicine or pharmacy' whilst providing that 'Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected ...'.

Allergan submitted that the provisions of Article 94 were transposed into English law by the Medicines (Advertising) Regulations 1994. Regulation 21 reproduced the prohibition on inducements to persons qualified to prescribe or supply medicinal products and the exemption for trade practices, dating the exemption from 1 January 1993, the date when the Directive came into force.

Allergan submitted that whilst the Panel's function was to deal with the Code and not the law, the provisions of the Code must be set in a proper context. The UK, as a Member State of the EU, had an obligation pursuant to the Treaty on the Functioning of the European Union (often referred to as the Lisbon Treaty) to ensure that the objectives of the Directive were attained. Article 97 allowed for self regulation and, therefore, pursuant to the Memorandum of Understanding made between the ABPI, the PMCPA and the MHRA, the MHRA did not intervene in self regulatory decisions made by the PMCPA except in rare circumstances.

Allergan submitted that it would be an unusual state of affairs if the Code purported to regulate aspects of the promotion of medicines which were expressly excluded from the European framework and its transposition into English law. Since the provisions of Title VIIIa of the Directive had been held by the Court of Justice in Luxembourg to be measures requiring complete harmonisation, Member States must ensure that the relevant local rules did not go beyond what was required by the Directive. It followed that in agreeing to self regulation by the PMCPA, the MHRA must have intended such self regulation to encompass those areas of pharmaceutical advertising dealt with by the Directive. The Directive expressly excluded existing 'trade practices, margins and discounts' from the scope of the prohibition on inducements to persons qualified to prescribe or supply them. Allergan submitted in order to give effect to the harmonizing aim of the Directive it was necessary to interpret the scope of this exemption in the same way throughout the EU, whether it was transposed into law or applied in a self regulatory context. This was not a case where the Code could properly provide definition to a principle contained in the law eg the meaning of 'inexpensive gift'.

Allergan, therefore, submitted that the Panel was wrong to suggest that the MHRA 'Blue Guide' had no relevance to its interpretation of the exemption from the scope of the Code provided for in Clause 1.2. The Blue Guide interpreted the exemption from the prohibition thus 'These are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts and similar offers such as "14 for the price of 12", provided they are clearly identifiable and invoiced.' Allergan's retrospective rebate scheme was a variety of volume discount scheme, as described above, and was clearly identifiable and invoiced. The Blue Guide made it clear that exempt trade practices did not have to be identical in every respect to schemes in existence on 1 January 1993 but might be 'similar'. Allergan's scheme was similar to volume discount schemes which it had demonstrated were in use before January 1993 and which corresponded to the MHRA's description of exempt schemes. The Panel found that there was an important difference between a rebate scheme and a discount. Allergan submitted that this was not a well founded distinction. All that Allergan's scheme did was to give money back to the NHS if it bought more than a certain number of products. It gave cash back after the purchase of a number of products as opposed to a lower price on the purchase of a number of products. The purchaser, in this case the NHS, had money refunded retrospectively rather than building the same amount up by way of savings prospectively, as would be the case with a discount. The ultimate result was the same. The NHS had more money to spend on its own priorities. In a market where there was no or low growth, such as glaucoma, a volume based discount had the same effect as a volume based rebate. In both cases, a growth in demand for Allergan's products inevitably lead to a decline in the demand for others. If a volume based discount was permissible, there was no reason to treat a rebate scheme any differently. Unless all the product required by a trust were to be supplied under one, yearly invoice, which was most unlikely, a volume discount necessarily would have to be calculated retrospectively. Allergan was aware that the MHRA did not treat rebates and discounts differently in relation to the Advertising Regulations, so long as they were transparently invoiced and accounted for.

Allergan submitted that the scheme should, therefore, be exempt from the scope of the Code and was an entirely commonplace commercial practice which provided a commercial benefit for it and the NHS. Neither European law nor UK law was intended to outlaw such practices, even where they applied to commercial dealings between persons qualified to prescribe or supply and sellers of pharmaceutical products. Where, as in the case of Allergan's scheme, the arrangement was a business to business dealing which did not purport to offer any financial benefit to individual prescribers the argument could be made with even greater force that it fell completely outside the permitted scope of the regulation of pharmaceutical advertising in the EU, whether by law or by a self regulatory body. Allergan noted that the Panel had ruled no breach of Clause 18.1 ie that the scheme did not offer individuals financial inducements.

The Panel appeared to find that because the scheme offered a rebate for prescribing in primary care where the prescription was initiated in secondary care it was a composite scheme which could not take the benefit of the exemption. Allergan had noted that, in effect, GPs merely prescribed the product chosen by the specialist ophthalmologist to whom they had referred their patient. Ophthalmological services in secondary care were largely commissioned by primary care organisations. Services would not be commissioned if they did not provide value to both parties. The fact that that NHS purchasing and commissioning structures had been reformed since 1993 should be immaterial to the Appeal Board's deliberations.

Allergan submitted that its scheme allowed the NHS to gain additional value in the purchase of its medicines and did not financially reward any individual. Pharmaceutical companies had offered such schemes, different in detail but identical in aim, since the inception of the NHS and continued to do so. The recent interest in patient access schemes to provide access to medicines that would otherwise be deemed by NICE too expensive for the NHS to buy, illustrated this well. A number of such schemes offered rebates, some offered discounts and others offered free products. Most based the receipt of these financial benefits on demonstrations of efficacy, in individual patients or more generally in the longer term. Innovative flexible pricing schemes were expressly encouraged by the DoH and the ABPI by the terms of the 2009 PPRS. No schemes identical in detail to these schemes were known in 1993. On the principles applied by the Panel in its ruling that Allergan's scheme breached the Code, all such schemes would also constitute such breaches. Allergan submitted that this could not be the right conclusion. A proper interpretation of the Code would exclude from its scope all such business to business schemes which did not induce individuals to prescribe.

In the event that the Appeal Board did not agree with Allergan's submission that its scheme was exempt from the scope of the Code, Allergan submitted that the retrospective rebate scheme did not breach Clause 18.5 of the Code. Clause 18.5 was added to the 2008 Code of Practice, together with Clause 18.6, ostensibly to comply with amendments to the EFPIA (European Federation of Pharmaceutical Industries and Associations) Code. There was nothing in the public pronouncements on the changes to the Code made in 2008 to suggest that it created an entirely new obligation on ABPI member companies or others who were subject to the Code. On its face it appeared to be a restatement and clarification of Clause 18.4 which provided that medical and educational goods and services might be provided subject to the provisions

of Clause 18.1 if they enhanced patient care or benefitted the NHS and enhanced [sic] patient care. Allergan submitted that its scheme clearly did not breach Clause 18.4 and no complaint had been made that it did. There was no provision of goods or services pursuant to the scheme and no provision of inducements to individuals contrary to Clause 18.1. Clause 18.5 provided that 'The provision of medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the Code) are only allowed if;

- they comply with Clause 18.4 or are made for the purposes of supporting research
- they are documented and kept on record by the company
- they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine'.

If the Appeal Board found that Allergan's retrospective discount scheme was subject to the Code then Allergan submitted that the circumstances of the scheme did not disclose a breach of Clause 18.5. The cash rebate paid into the NHS organisation's business account was not a grant or a donation in the nature of a provision of goods or services of a medical or educational nature; it was a commercial rebate. A grant or donation implied that money was given without condition and not in exchange for something. It was simply a gift. Allergan's cash rebate was a business arrangement whereby the rebate was given in exchange for a particular number of purchases. It is not a donation or grant or a gift and was not treated in Allergan's accounts as such. It was a rebate on the sale price of the products in question.

Allergan submitted that the Panel's ruling of a breach of Clause of 18.5 was predicated on its conclusion, which did not appear to be based on any preceding reasoning or evidence, that the rebate scheme in effect could be seen as donation, grant or benefit in kind. In common parlance as well as in law a donation was distinguishable from a contractual payment in that it was not made consequent upon any agreement imposing an obligation that it should be paid or on a right to receive it. A donation was a gift; a cash rebate was not a gift. A cash rebate became due if the terms of a pre-existing contract gave rise to an obligation requiring its payment by one party to the other. Allergan had entered into an agreement with NHS organisations that the rebate would be paid if certain target sales volumes were reached. This was a contractual payment and not a donation. It was not prohibited by Clause 18.5. This analysis was supported by advice published by the PMCPA on its website commenting on joint working arrangements between the pharmaceutical industry and the NHS. The Allergan scheme was clearly not a joint working arrangement as it did not meet the required criteria laid out in the ABPI Guidance Notes on Joint Working between Pharmaceutical Companies and the NHS and Others for the Benefit of Patients (March 2009). However, the PMCPA advice provided additional interpretation of Clauses 18.5 and 18.6 and was not confined to their application to joint working arrangements. The advice stated:

> 'Clause 18.5 relates to donations and grants etc and not to activities involving the sale of medicines.
>
> It seems that Clause 18.5 would have no application to arrangements where goods and/or services are provided as part of an agreement between an institution and a company which involves the sale of medicines by the company to the institution.'

Allergan submitted that this advice was correct and meant that Allergan's retrospective rebate scheme, which was an arrangement involving the sale of medicines by the company to the institution, could not give rise to a breach of Clause 18.5. Allergan submitted that the proper interpretation of Clause 18.5 was that grants and donations to organisations which provided healthcare must benefit the NHS and must not constitute an inducement by way of a gift, benefit in kind or pecuniary advantage to a the health professional. It would then represent a helpful clarification of, and be entirely consistent with, both Clauses 18.1 and 18.4, and would prohibit donations to organisations which, in fact, turned out to provide a benefit to individual health professionals. It was not intended to prevent business rebates and the concern that this should be clear was evident from the PMCPA's advice which was particularly directed to ensure that innovative funding arrangements, such as the scheme at issue which provided value to the NHS were not outlawed by the Code.

If the Appeal Board found that there had been no breach of Clause 18.5 then the findings of breaches of Clauses 9.1 and Clause 2 fell away. In the event that the Appeal Board ruled a breach of Clause 18.5 then Allergan submitted that any such breach was not so severe as to warrant a finding that high standards had not been maintained or that confidence in the pharmaceutical industry had been reduced. The scheme was totally transparent and formed the basis of a commercial contract between an NHS organisation and Allergan. These arrangements would have been reviewed and approved at a senior management level at each participating trust. There had been no complaints from any of the trusts. The scheme fell squarely within the type of schemes permitted by the document published by the DoH in 2000 entitled 'Commercial sponsorship - ethical standards for the NHS' which stated:

> 'PCGs, health authorities and primary care contractors will need to consider issues such as:
> ....
>
> Purchasing decision, including those concerning pharmaceutical and appliances, should always be taken on the basis of best clinical practice and

value for money. Such decisions should take into account their impact on other parts of the health care system, for example, products dispensed in hospital which are likely to be required regularly by patients at home.

Hospital trusts who are offered significant discounts on drugs may wish to consult the relevant PCG/PCT about possible implications for subsequent prescribing in primary care.'

An example was given of a situation where a manufacturer of a particular type of nicotine replacement therapy offered to provide its product at a reduced rate to a Health Action Zone or a health authority. It was stated that 'This arrangement is acceptable provided that there is a clear clinical view that these products are appropriate to particular patients and there is no obligation to also prescribe these products to other patients for whom an alternative product would be equally beneficial'.

Allergan submitted that its scheme did not require any of its products to be prescribed. The rebate was only paid if sufficient numbers of products were prescribed, but there was no obligation to prescribe them. The decision rested with the individual clinician. If Allergan's scheme met the ethical standards of the NHS set by the DoH, participating trusts being well aware of their responsibility to liaise with primary care prescribing, Allergan submitted that the scheme could not be judged to have failed to maintain high standards or brought discredit on the pharmaceutical industry.

COMMENTS FROM ALCON

Alcon alleged that under the scheme, NHS organisations were granted a retrospective cash rebate which was to be held in a trust fund for the provision of ophthalmic services, together with a package of support, provided that prescriptions of Allergan's products reached a certain unit market share threshold within a particular geographical area. The majority of NHS organisations would not be entitled to any retrospective rebate (let alone the highest level of rebate), unless they displaced competitor products (by the questionable approach of switching patients unnecessarily who were currently well controlled on a non-Allergan product to an Allergan-product). In promoting the scheme, Allergan had not maintained high standards and its activity brought discredit upon or, at the very least, reduced confidence in the pharmaceutical industry.

Alcon noted that in its response, Allergan had set out what it considered to be the essential elements of the scheme. However, rather than presenting an objective summary of the facts, Allergan had made several disingenuous remarks which warranted comment as explained below (for ease Alcon had followed the order of Allergan's bullet points).

- In the 1st bullet, Allergan characterised its share in the glaucoma market as minor.

Alcon alleged that in this context, it should be noted that entitlement to the retrospective rebate depended on the NHS organisation attaining a significant to major share of the market. As Allergan acknowledged, the glaucoma market was subject to slow growth with very few new entrants, which meant that the only means of securing a greater market share was to decrease the share held by competing products. Consequently, patients must be switched from a non-Allergan product to an Allergan product in order to reach the required threshold to obtain the retrospective rebate.

- In the 2nd bullet, Allergan explained that the prescription of glaucoma products was initiated by ophthalmic specialists in secondary care and that whilst repeat prescriptions were often provided in primary care, there was little or no opportunity for a GP to initiate or change a patient's medication, as he or she would seldom be required to make that decision.

Alcon alleged that Allergan appeared to suggest that in so far as the scheme was promoted to PCTs, it would not trigger an increase in prescriptions of Allergan's products. However, it was clear from Allergan's briefing document for representatives that its strategy in relation to primary care was to target those organisations which had the capacity to influence prescribing. Indeed, it was stated under the heading 'Step two (primary care)' in the action list: 'Capability of commissioned organization to influence prescribing is assessed' which could imply that if they were not capable of influencing prescribing then they should not be involved. This document set out instructions for representatives in the form of 'Actions to get started'; step two had two limbs – an approach for hospitals and an approach for primary care.

Alcon further alleged that GPs were expected to follow the PCT or practice guidance (or formulary where available) with regards to prescribing. Although the choice of what to prescribe was ultimately at the clinical discretion of the GP, GPs would know that the PCT might not increase the practice's annual medicine budget if the practice ran up a significant medicine bill (and this was seen to be a consequence of the under-prescribing of medicines listed in the formulary or guidance). It appeared that Allergan was specifically targeting those primary care organisations which would be effective in influencing prescribing, GPs would face pressure to switch patients from a non-Allergan product to an Allergan product in order to achieve the unit market share threshold.

- In the 6th bullet, Allergan stated that the retrospective rebate thresholds were expressed as a percentage of unit (rather than value) market share in order not to discriminate against organisations serving small geographical areas or with a sparse population.

Alcon alleged that Allergan seemed to imply that structuring the scheme on the basis of unit market

share targets was the only way that PCTs and hospital trusts which served the needs of small patient populations could benefit from a favourable price agreement. However, a pricing agreement did not have to (and should not) be structured such that its success depended on displacing competitors' products. Indeed such NHS organisations could alternatively benefit from a standard volume based discount which would not operate as an inducement (eg 'buy x amount and get y amount free'), provided that 'x' was actually based on a realistic purchasing target.

Alcon alleged that further, it appeared that the unit market share thresholds under the scheme were not adjusted as between different geographical areas in order to take account of the 'natural' market conditions (ie in the absence of the scheme). This meant that NHS organisations in some geographical areas would have to significantly increase prescribing levels for Allergan products in order to meet even the lowest unit market share threshold.

- In the 7th bullet, Allergan stated that the lowest market share threshold was set to reflect the range of existing observed prescribing levels across a range of trusts.

Alcon alleged that notably, Allergan did not comment on the higher market share thresholds which did not generally reflect existing observed prescribing levels. Clearly, NHS organisations participating in the scheme would want to meet the highest threshold in order to benefit from a major financial retrospective rebate at the end of the accounting period.

- In the 8th bullet, Allergan asserted that no NHS organisation was required to agree to prescribe Allergan's products in order to take part in the scheme. Allergan's products needed only to be available as an option for ophthalmic specialists to prescribe if it judged them to be suitable for any particular patient. Alcon alleged that this statement was misleading. The relevant point was that an NHS organisation was required to attain a certain level of prescriptions (calculated as market share) in order to derive the real benefit from the scheme (namely, the retrospective rebate). *De facto*, NHS organisations were required to prescribe Allergan products (or recommend these products for prescription). Further, and as explained below in relation to the final bullet, the provision of educational services was linked to the prescription of Allergan products.

- In the 12th bullet, Allergan stated that it had no influence and, in most cases, no knowledge of the way in which the funds were used. Nevertheless, it should be noted that the scheme provided a collateral benefit for participating NHS organisations, namely the means '... to develop ophthalmic services in the community and or for the benefit of patients with ophthalmic conditions' as stated in the agreement by way of a trust fund. The composite nature of the scheme (retrospective cash rebate plus administration of trust fund) was a factor of relevance in the Panel's ruling on Clause 18.5.

- In the 13th bullet, Allergan claimed that the provision of educational services to NHS organisations signing up to the scheme was not linked to any level of prescriptions for its products or any prescriptions at all. The provision of educational services was not linked to any claim for a rebate on purchases. Alcon alleged that clearly, however, the provision of educational services was *de facto* linked to prescriptions for Allergan products and a retrospective rebate on purchases. The objective of the scheme was to increase prescriptions for Allergan products; the educational services were provided to facilitate this objective (indeed, such services were provided to participating units, as stated in Allergan's 'Retrospective Rebate Initiative – Briefing Document for Representatives', under 'Step four').

Why the scheme was not exempt from the Code

Alcon alleged that the primary basis for Allergan's appeal was that the scheme fell outside the scope of the Code because it was an example of a measure or trade practice relating to prices, margins and discounts in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 (and was therefore exempt under Clause 1.2). Further, Allergan argued that this exemption should be understood within the context of the prohibition on inducements to individual persons qualified to prescribe in accordance with Article 94 of Directive 2001/83/EC (as amended) (the 'Directive'), as transposed into English law by Regulation 21 of the Medicines (Advertising) Regulations 1994 (the 'Regulations'). Thus, Allergan argued that:

- the scheme was not subject to the Code on the basis that it benefitted from the Clause 1.2 exemption; and
- in any event, it did not breach Clause 18.5 because the retrospective rebate was not a donation or grant within the meaning of Clause 18.5 and, further, that clause prohibited only financial inducements to individual members of the health profession.

Alcon alleged that in support of its argument, Allergan resorted to challenging the very nature of self regulation. Allergan commented that it would be an unusual state of affairs if the Code purported to regulate aspects of the promotion of medicinal products which were expressly excluded from the European framework and its transposition into English law. However, the aspects of the Code to which Allergan referred did not purport to regulate aspects of the promotion of medicinal products which were 'expressly excluded' from the European legal framework (which had been transposed into English law). This was explained below in relation

to a) the scope of the Clause 1.2 exemption; and b) the scope of the Clause 18.5 prohibition.

The scope of the Clause 1.2 exemption

Alcon noted that the Code excluded from its scope 'measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993'. This was a general exemption and, if applicable in the present case (which Alcon refuted), would take Allergan's scheme outside the scope of the Code entirely. Article 94(4) of the Directive provided a similar exemption in the context of the provision regarding inducements (for ease of reference, Article 94 was set out in full below):

1. 'Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.
2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than healthcare professionals.
3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.
4. **Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3'** (emphasis added).

Article 94 has been transposed into English law by Regulation 21 of the Advertising Regulations; Regulation 21(4) provided that 'Nothing in this regulation shall affect measures or trade practices relating to prices, margins or discounts which were in existence on 1st January 1993'.

Alcon alleged that it was clear from the above that the Code's Clause 1.2 exemption was narrower than the Article 94(4)/Regulation 21(4) exemption: whereas the Code provided that only those measures and trade practices 'in **regular** use by a **significant proportion** of the pharmaceutical industry on 1 January 1993' (emphasis added) were exempt, the Directive and Regulations excluded from their scope all measures and trade practices which were merely 'in existence' on 1 January 1993. The Directive was a consolidation of various previous Directives, including Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use which came into force on 1 January 1993. This was why 'existing' (ie existing as at 1 January 1993) measures or trade practices in Member States relating to prices, margins and discounts were excluded from the prohibition on inducements. Clearly, the scheme was novel (and was not in existence – let alone in regular use - as at 1 January 1993); indeed, it was acknowledged by Allergan to be 'innovative' in the Executive Summary to the Scheme Agreement (as explained in Alcon's complaint). The factors which the Panel took into account in deciding that the scheme did not benefit from the Clause 1.2 exemption (namely, the scheme's composite nature, and the fact that many NHS organisations would have to increase their prescribing to benefit from the retrospective rebate) were discussed further below.

Further, contrary to Allergan's suggestion, Alcon alleged that this did not mean that the Code was regulating aspects of the promotion of medicinal products expressly excluded by the EU legal framework. Firstly, it had already been explained above that the scheme did not benefit from the exemption in the Directive/Regulation, or in the Code. Secondly, it had been clearly established that the Code extended beyond UK legal requirements (implementing the Directive), which was entirely legitimate (contrary to what Allergan argued). Indeed, Article 97(5) of the Directive stated that the provisions regarding the monitoring, vetting and legal action that might be taken in relation to advertising '... shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1'. Accordingly, the Directive specifically did not exclude the self-regulation of advertising and, moreover, did not limit the scope of self-regulation. Indeed, as stated on the PMCPA's website 'In addition to the Code, there is extensive UK and European law relating to the promotion of medicines. The Code **reflects and extends beyond the legal requirements** controlling the advertising of medicines' (emphasis added). Further, the Memorandum of Understanding between the ABPI, PMCPA and MHRA specifically acknowledged that: 'The ABPI Code covers and extends beyond UK law and it is thus possible that material pre-vetted and approved by the MHRA might subsequently be ruled in breach of the ABPI Code'.

For this reason, the Memorandum of Understanding established that: 'The MHRA will also refer complaints about relevant matters not covered by UK law to the PMCPA for consideration under the ABPI Code'.

Alcon alleged that clearly, therefore, the purpose of the Code was not limited to providing detail on principles enshrined in the legislation as Allergan claimed; rather, the scope of the Code extended beyond the law, which was why material which did not fall foul of the UK law (and the MHRA's Blue Guide) might nevertheless be found in breach of the Code. Accordingly, the Panel applied the correct standard in assessing whether Allergan's Scheme was of a type in regular use by the pharmaceutical industry. The reason why the PMCPA did not accept that the Scheme benefitted from the Clause 1.2 exemption was its composite nature (namely, retrospective cash rebate plus administration of subsequent trust fund): 'Allergan had provided no

evidence that such composite schemes were in regular use by the pharmaceutical industry prior to 1 January 1993. The Panel considered that such composite schemes could not take the benefit of the exemption. The scheme was thus subject to the Code'.

Alcon noted that Allergan had stated that the Panel appeared to find that the fact that the scheme offered a rebate for prescribing in primary care where the prescription was initiated in secondary care rendered it a composite scheme which could not take the benefit of the exemption. In this regard Allergan appeared to have misunderstood the Panel's ruling; the scheme was composite because it consisted of a retrospective rebate plus administration of a trust fund. The fact that the scheme linked primary care prescribing volumes to products where prescribing was usually initiated in secondary care was however relevant to the Panel's finding that the arrangement was inappropriate (the scheme sought to influence primary care prescribing patterns).

The Panel also noted that there was an important difference between a cash rebate and a discount. Allergan disputed this distinction, and argued that the ultimate result was the same. The NHS had more money to spend on its own priorities. Allergan submitted that in a market where there was no or low growth, such as glaucoma, a volume based discount had precisely the same effect as a volume based rebate. In both cases, a growth in demand for Allergan's products inevitably led to a decline in the demand for others. Alcon alleged that Allergan's statement was misleading because it oversimplified the circumstances at stake. The present case was not straightforward: the retrospective rebate did not operate like an 'inverse' discount - in other words, the issue was not whether, for example, '14 for the price of 12' (standard discount) was different in principle from 'Buy 14 and get a refund for 2' (standard retrospective rebate). The important difference identified by the Panel between Allergan's retrospective cash rebate and a standard discount was that, as explained above, the scheme was composite – which meant that it did not provide cash to the payer (the NHS) as a standard discount (or even a standard rebate) would. Rather, the retrospective rebate took the form of a fund which might be applied at the discretion of the fund managers (which was also relevant to the breach of Clause 18.5, as explained below). It was noted that the Panel distinguished the scheme from the examples provided by Allergan on the basis that Allergan had provided no evidence that such composite schemes were in regular use by the pharmaceutical industry prior to 1 January 1993.

Further, the Panel assumed, from the market details provided that **many areas would have to increase their prescribing of Allergan's products in order to reach the first threshold and thus qualify for a rebate**. Four areas had signed up to the scheme of which two had unit shares above the first threshold one above the second threshold and the other just below the first threshold. The Panel considered that **insofar as the scheme encouraged the trust to persuade prescribers to increase their prescribing so that the trust could gain a cash rebate, or increase its cash rebate, it could be interpreted as an inducement'** (emphasis added).

Alcon alleged therefore that the scheme's structure (which was based on unit market share - meaning that it is necessary for the NHS organisation to displace competitors' products in order to benefit from the retrospective rebate) appeared to be another factor which the Panel took into account in deciding that the arrangement could not benefit from the Clause 1.2 exemption. Thus, Allergan's claim that its scheme achieved the same 'ultimate result' as a standard discount was incorrect. Whilst it was true that, as Allergan submitted that, a growth in demand for its products inevitably led to a decline in the demand for others, the way in which the scheme was structured meant that its psychological effect would be different to that of a standard discount scheme. As explained in Alcon's complaint, there would be particular areas with more than participating NHS organisation (London was one example); in such cases the risks associated with the scheme would be even more pronounced as organisations would compete with each other to meet the thresholds required to obtain the retrospective rebate for Allergan's glaucoma products. As one organisation would not know what threshold had been achieved by the other NHS organisation(s) in that area, it was likely to over-compensate by adopting strategies to significantly increase its own market share for Allergan products so that it was best placed to obtain the retrospective rebate itself. Alcon submitted that Allergan had likened the scheme to a patient access scheme but ignored cost comparisons and considerations of alternative therapies. The driver of the scheme would therefore be the rebate which could result in undue pressure being put onto prescribers who would have little understanding of the impact of their prescribing on achieving the overall threshold. In this respect it would be possible for them to 'over-prescribe' products within the scheme.

Alcon alleged that therefore, in spite of Allergan's insistence on the fact that the scheme was totally transparent, the need to attain a certain unit market share threshold created uncertainty (and would, in some circumstances, be dependant on the success of other NHS organisations within the same geographical area taking a share of the market for Allergan products). Indeed, as explained in Alcon's complaint, the risk associated with annual fund payments was that participating NHS organisations might be tempted to prescribe more Allergan products than was necessary to obtain the retrospective rebate because the long accounting period would give rise to uncertainty (notwithstanding the provision of quarterly reports showing unit market share).

Finally, Alcon noted that Allergan had commented

on the recent interest in patient access schemes and innovative flexible pricing schemes, none of which were identical to the schemes that were known in 1993. Allergan concluded that on the principles applied by the Panel in its ruling that Allergan's scheme breached the Code, all such schemes would also constitute such breaches. Allergan submitted that this could not be the right conclusion.

Alcon alleged that Allergan's comment was misleading. Indeed, Allergan misrepresented the implications of the Panel's ruling, jumping to the conclusion that all novel schemes (whether patient access schemes or innovative flexible pricing schemes) would breach the Code. Thus Allergan seemed to conclude that all schemes subject to the Code would also breach the Code; these were however two different issues which Allergan incorrectly conflated by concluding its discussion of the Clause 1.2 exemption with the above statement. In the present case, Alcon agreed with the Panel's ruling that Allergan's scheme was both subject to the Code and in breach of it (because it operated as an inducement to prescribe Allergan's glaucoma medicines). However, this was not to say that any novel scheme would be in breach of the Code; it would depend on the specific circumstances. For example, in the case of an outcome or risk sharing agreement, the PMCPA's guidance on 'Joint working and the ABPI Code of Practice for the Pharmaceutical Industry' provided that such arrangements are acceptable so long as certain conditions were met. In such cases, a refund or recompense paid to a health authority or trust would not constitute an inducement to prescribe because the company did not pay for prescriptions (rather, it provided a refund/recompense where the therapeutic effect did not meet expectations). Accordingly, the scheme did not benefit from the Clause 1.2 exemption and was subject to the Code.

The scope of the Clause 18.5 prohibition

Alcon noted that Allergan further submitted that even if the scheme was held to fall within the scope of the Code, it did not breach Clause 18.5 because the retrospective rebate did not constitute a donation or grant within the meaning of Clause 18.5 and, further, that clause prohibited only financial inducements to individual members of the health profession. Alcon's substantive comments on this point were set out below (Alcon strongly disagreed that Clause 18.5 was indeed limited in the ways Allergan argued). However, Alcon alleged that it first should be noted that the Clause 18.5 prohibition of inducements to institutions, organisations or relevant associations was not, as Allergan claimed 'expressly excluded' from the European legal framework (which had been transposed into English law). In this regard, Alcon's comments above applied concerning the relationship between the legal and self-regulatory regimes.

Breach of Clause 18.5

Alcon noted that Allergan's appeal on Clause 18.5 was focussed on the argument that the scheme did not fall within the scope of that clause. Allergan did not specifically address whether the scheme was an inducement in the event that the Appeal Board agreed with the Panel and with Alcon that Clause 18.5 was applicable to the arrangement.

Allergan disputed the Panel's characterisation of the retrospective rebate as a donation, grant or benefit in kind on the basis that it was a contractual payment which must be paid if certain target sales volumes were reached. Alcon alleged that firstly, and as explained below, the retrospective rebate was not given in isolation; as the Panel noted, Allergan provided a 'package of support' in addition to the retrospective rebate and, further, the scheme was composite in nature (retrospective cash rebate plus administration of subsequent trust fund). Therefore, Allergan oversimplified the Scheme by characterising it as a simple contractual payment; the scheme was in fact multi-faceted. Secondly, Allergan could not escape the scope of Clause 18.5 on the basis that the retrospective rebate - which itself triggered associated benefits - was given in exchange for the achievement of a certain unit market share for Allergan products. Indeed, the contractual promise of a retrospective rebate under the scheme was precisely one of the reasons why the scheme constituted an inducement to prescribe. NHS organisations were directly induced to prescribe/recommend/buy etc Allergan products - and to displace competing products - in order to obtain the retrospective rebate, the package of support and the means of developing ophthalmic services in the community.

Allergan also relied on the PMCPA's guidance which stated that: 'Clause 18.5 relates to donations and grants etc and not to activities involving the sale of medicines'. However, as noted above, that statement must be read in its proper context. The guidance in fact stated that Clause 18.5 would not impact upon joint working because it related to donations and grants and not to activities involving the sale of medicines; however, the guidance further stated that: 'If the company's medicines were not sold as part of the joint working, **Clause 18.5 might apply**' (emphasis added). As Allergan acknowledged, the present arrangements were clearly not part of joint working; therefore, in principle, Clause 18.5 was relevant (and, moreover, was applicable in the present case, as explained further below). The fact that activities involving the sale of medicines (ie under contractual arrangement) might fall within the scope of Clause 18.5 further supported the argument that Allergan could not escape liability on the basis that the retrospective cash rebate element of the scheme was given under a contractual obligation.

Allergan stated that the Panel's conclusion (that the scheme in effect could be seen as a donation, grant or benefit in kind) did not appear to be based on any preceding reasoning or evidence. However, Alcon alleged that the Panel's ruling in this respect was reasoned; the Panel noted that a package of

support was provided to the NHS organisation in addition to the cash rebate which was inextricably linked to the promotion of Allergan's glaucoma medicines. Further, the Panel's reasoning in respect of the Clause 1.2 exemption was also relevant in this regard. Indeed, and as discussed above, the Panel characterised the scheme as composite in nature because it consisted of a retrospective cash rebate and the administration of a trust fund. Thus it provided a collateral benefit ie the means '... to develop ophthalmic services in the community and or for the benefit of patients with ophthalmic conditions' as stated in the agreement (the fact that Allergan claimed to have no influence and, in most cases, no knowledge of the way in which the funds were used was not relevant to the Clause 18.5 assessment).

Allergan further submitted that Clause 18.5 (which was introduced in 2008) was not intended to create an entirely new obligation on ABPI member companies or others who had elected to be subject to the Code. According to Allergan, Clause 18.5 was a restatement and clarification of Clause 18.4 and – in order to be consistent with Clause 18.1 - should be interpreted as prohibiting only donations, grants and benefits in kind which constituted an inducement to individual members of the health profession. However, Allergan did not appear to have any basis for its assertion that Clause 18.5 was not intended to create an entirely new obligation; indeed, if it was not intended to create a new obligation, it would be redundant (the same applied for Clause 18.6). Further, the supplementary guidance to Clause 18.5 specifically stated that 'donations and grants to health professionals are not covered by this clause' (presumably because they were covered by Clause 18.1). Clause 18.5 clearly prohibited the provision of donations (etc) to institutions which constituted an inducement to that institution; it simply did not make sense to say that it prohibited donations which constituted an inducement to individual health professionals. Indeed, the concept of 'inducement' had no meaning within the context of Clause 18.5 unless the donee and the person induced were one and the same (namely, the institution).

For the sake of completeness, Alcon alleged that Allergan's specific comments on the inter-relation between Clauses 18.5, 18.4 and 18.1 were unfounded and did not support its argument that Clause 18.5 was limited to the inducement of individuals. Indeed, it appeared that Allergan had argued that because Clause 18.5 referred to Clause 18.4 (which in turn referred to Clause 18.1) that the Clause 18.5 prohibition on inducements was limited to the provision of inducements to individuals. However, Clause 18.4 was only relevant in defining the allowable purpose of medical and educational goods and services (MEGS). Accordingly, Clause 18.5 provided for the relevant part that the provision of MEGS in the form of donations, grants and benefits in kind were only allowed if 'they comply with Clause 18.4 or are made for the purpose of supporting research'. Accordingly, if such donations/grants/benefits in kind were not made for the purpose of supporting research, they must – under Clause 18.4 'enhance patient care, or benefit the NHS and maintain patient care'. Therefore, the reference to Clause 18.4 in Clause 18.5 was only of relevance in defining the allowable purpose of MEGS; it did not suggest that the prohibition on inducements was limited to its Clause 18.1 meaning (which the PMCPA had decided was not applicable in this case). Quite the contrary, Clause 18.5 specifically provided that MEGS in the form of donations, grants and benefits in kind were only allowed if 'they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine'. If as Allergan suggested Clause 18.5 should be interpreted as subsidiary to Clause 18.4/18.1, there would be no reason for the Code to specifically state that MEGS in the form of donations/grants/benefits in kind might not constitute an inducement to prescribe. Accordingly, by specifically stating that donations/grants/benefits in kind to institutions etc might not constitute an inducement to prescribe, the Code clearly prohibited inducements to such institutions.

Alcon alleged that offering an inducement to an NHS organisation, such as a PCT, might trigger that PCT to introduce financial inducement systems aimed at medical practices (which ultimately benefitted GPs who shared in the profits made by the practice). The ABPI had declared that the operation of such schemes by PCTs violated Article 94(1) of the Directive; the ABPI's case against the MHRA on this point was currently pending before the European Court of Justice.

Accordingly, Alcon alleged that as the Panel found, the scheme in effect operated as a kind of donation, grant or benefit in kind and should comply with Clause 18.5. However, the Scheme fell foul of Clause 18.5 because the retrospective rebate was inextricably linked to the promotion of Allergan's glaucoma medicines such that it amounted to an inducement to buy, recommend and prescribe those medicines.

Breach of Clauses 9.1 and 2

Alcon disagreed with Allergan's statement that if the Appeal Board ruled no breach of Clause 18.5 then the breaches of Clauses 9.1 and Clause 2 fell away. Nothing in the wording of either Clause 2 or Clause 9.1 suggested that they must be linked to other breaches of the Code. Clause 2 provided that 'Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry'. The clause was therefore very broadly worded and encompassed any activity/material 'associated with promotion'. Although Clause 2 was normally reserved for cases of particular censure and, for this reason, typically followed one or more other breaches of the Code, there was no reason why, in principle, Clause 2 could not be ruled in isolation or in conjunction with Clause 9.1. Even if the Appeal Board were to find that the scheme fell outside the

scope of the Code as a whole or outside the scope of Clause 18.5, it might nevertheless consider that the scheme constituted an unacceptable inducement to prescribe. Indeed, the scheme induced NHS organisations to displace competitors' products, by irrationally switching patients who were currently well controlled on a non-Allergan product to an Allergan-product, in order to obtain a retrospective rebate and associated package of support. As explained above, the scheme was structured to create uncertainty amongst NHS organisations and its psychological effect was very different from that of a standard discount/rebate. Thus, whether or not the Appeal Board considered that the scheme breached Clause 18.5, Allergan's activity should not be tolerated if it brought discredit upon, or reduced confidence in, the pharmaceutical industry. With regard to Clause 9.1, this was very broadly worded and not linked to any other provision in the Code ie 'High standards must be maintained at all times'.

Alcon noted that the Panel had previously found companies to be in breach of Clause 9.1, even where no other breach of the Code was ruled. By example in Case AUTH/2175/10/08 (Anonymous General Practitioner v ProStrakan) regarding an osteoporosis audit service; breaches of Clause 9.1 were ruled, but no other breach of the Code.

Alcon alleged that clearly, it was not compatible with high standards to operate a scheme which, as explained above, induced NHS organisations to displace competitors' products in order to obtain a retrospective rebate and associated package of support. Allergan's aggressive approach was evidenced by its briefing document for representatives. As explained above, this briefing document sets out 'Actions to get started'; step one stated that the formulary status of all three glaucoma products had to be determined and representatives were instructed that if one or more products was not on the formulary they must take 'immediate action to gain formulary listing'. Further, under 'Step two (primary care)', the representatives were instructed to assess the 'capability of commissioned organization to influence prescribing' (as explained above, this suggested that those organisations which could not influence prescribing should be excluded from the scheme). Alcon alleged that Allergan's assertion that the scheme did not require any of its products to be prescribed and that the decision rested with the individual clinician was disingenuous because, as explained above, an NHS organisation was required to attain a certain level of prescriptions, calculated as market share, in order to derive the real benefit from the scheme ie the retrospective rebate. Allergan effectively used the scheme to encourage NHS organisations to displace competing products, with the consequence that patients might not be prescribed the most appropriate medicine. Allergan referred to the DoH's document entitled 'Commercial sponsorship – ethical standards for the NHS' and cited the example of a situation where a manufacturer of a nicotine replacement therapy offered to provide its product at a reduced rate to a Health Action Zone or a health authority. In this context, Allergan quoted the DoH's statement that 'This arrangement is acceptable provided that there is a clear clinical view that that these products are appropriate to particular patients and there is no obligation to also prescribe these products to other patients for whom an alternative product would be equally beneficial'.

Alcon alleged, however, that the example concerned a standard discount where there was no inducement to prescribe; it was therefore not relevant to the present situation. The scheme, on the other hand, operated as an inducement with the consequence that the status quo (where clinicians had the discretion to prescribe the most appropriate product for the individual patient) was subverted. *De facto*, if an NHS organisation wanted to obtain the retrospective rebate (which was the only reason it would enter into the agreement with Allergan), it would be obliged to prescribe, or recommend for prescription, Allergan products to patients for whom an alternative product would be equally beneficial in order to meet the unit market share thresholds (or even to switch patients from another product that previously had been considered the appropriate treatment). Further, Allergan denied a breach of Clauses 9.1 and 2 on the arbitrary basis that interpretation of the Code was a difficult area and was not straightforward. Allergan submitted it would be unduly harsh to rule that if Allergan's interpretation was at odds with the Panel's this should constitute a failure to maintain high standards or actions likely to reduce confidence in the pharmaceutical industry. In Alcon's view application of Clauses 9.1 and 2 was not limited to straightforward breaches of the Code; the applicable standard was the severity of the conduct.

Alcon was concerned that Allergan's scheme would set a major precedent for the pharmaceutical industry and would imply to the medical community and the public that it was legitimate for pharmaceutical companies to pay for prescriptions. This would discredit the pharmaceutical industry and potentially cause a government backlash. Accordingly, in light of the above, Alcon maintained that Allergan's grounds of appeal were unfounded and should be rejected.

APPEAL BOARD RULING

The Appeal Board considered that although the scheme at issue contained elements of trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993, and which were otherwise exempt from the Code, the way in which the scheme operated as a whole meant that it had gone beyond that exemption and was thus subject to the Code.

The Appeal Board noted that the scheme was based upon a volume based percentage market share ie the amount of rebate due depended upon the

number of bottles of Allergan products prescribed. This was confirmed by Allergan at the appeal. The Appeal Board further noted that the representatives' briefing material stated that the territory managers would support participating units with appropriate educational events and meetings. Alcon however, confirmed at the appeal that it had no evidence to show that the provision of educational events and meetings was exclusively linked to the retrospective rebate scheme.

The Appeal Board considered the applicability of Clause 18.5 and noted that in its view the rebates paid were a contractual financial arrangement. The amount paid was conditional on obtaining certain thresholds of market share. In that regard the Appeal Board did not consider that the rebate was a medical and educational good or service in the form of a donation, grant or benefit in kind. The Appeal Board thus ruled no breach of Clause 18.5.

The Appeal Board was concerned that the scheme could be perceived as an inducement to prescribe Allergan's products. The Appeal Board noted that generally such schemes might result in more prescriptions of a company's product. That was not necessarily unacceptable as long as the arrangements complied with the Code. The question to be established was whether the scheme amounted to an inappropriate inducement. A primary care organisation would potentially qualify for a larger cash rebate if its prescribers increased the number of packs of Allergan products they prescribed. Whilst it was true that one way to do this would be to switch from another company's medicines, nonetheless, the Appeal Board noted that there was no evidence of undue pressure on individual prescribers to do this. On the merits of this particular case the Appeal Board decided that Allergan had not failed to maintain high standards. No breach of Clause 9.1 was ruled. The Appeal Board subsequently ruled no breach of Clause 2. The appeal was successful on all points.

Complaint received **7 October 2009**

Case completed **24 February 2010**

* * * * *

During its consideration of this case the Panel sought advice from Mr Alan Sheppard, BTech (Hons), Managing Director, Ascher Resources Ltd, who provided an opinion in a personal capacity.