ANONYMOUS v NICOVENTURES

Call rates pre-licence

The Medicines and Healthcare Products Regulatory Agency (MHRA) at the request of a complainant referred his/her complaint about call rates for sales teams which was a matter not covered by UK legislation to the PMCPA.

The complainant noted that Nicoventures was currently awaiting a licence for a nicotine replacement therapy (NRT) product and that a reliable source, had informed him/her that the company had set a call rate for health professionals for its sales teams which he/she believed was against the Code in relation to marketing unlicensed products.

The detailed response from Nicoventures is given below.

The Panel noted that Nicoventures was awaiting a marketing authorization for its nicotine-containing product, Voke. The Code allowed those responsible for making policy decisions on budgets to be provided with advance notification of new medicines which would have a significant budgetary impact.

The Panel noted a slide included in a marketing strategy presentation for the healthcare development managers (HDMs) was headed 'Nicoventures Incentive Scheme'. Under a sub-heading of 'Part 1 (GAP analysis): Completion of the following parameters' was listed 'Identification of customers', 'Identification of local guidance documents' and 'Conducting Budget Holder Meetings'. In that regard the Panel noted that a component of the HDMs incentive scheme was linked to conducting meetings. On the left-hand side of the slide, however, it was stated 'No activity measure as a qualifier'. In the Panel's view it was not necessarily unacceptable to include meetings in the HDMs' incentive scheme. The Code recognised that advance notification was appropriate in certain situations; there was no requirement that such information could only be provided reactively.

The Panel considered that as there was no prohibition in the Code with regard to setting call rates for the delivery of advance notification to health professionals, to do so did not, in itself, amount to promotion of a product prior to the grant of a marketing authorization. On the narrow grounds of the complaint, no breach of the Code was ruled. The Panel did not consider that there was any evidence to show that the frequency, time and duration of calls made by the HDMs had caused inconvenience. No breach of the Code was ruled. With regard to call rates the Panel did not consider that the HDMs' briefing material advocated either directly or indirectly any course of action which was likely to lead to a breach of the Code. No breach of the Code was ruled.

The Panel noted its ruling above and did not consider that high standards had not been maintained. No breach of the Code was ruled including no breach of Clause 2.

The Medicines and Healthcare Products Regulatory Agency (MHRA) at the request of a complainant referred his/her complaint to the PMCPA. The MHRA noted that the complaint concerned call rates for sales teams which was a matter not covered by UK legislation. The MHRA also noted that it had recently investigated a complaint that Nicoventures had promoted an unlicensed product to budget holders and it provided a copy of its report on the matter. The complaint to the MHRA was not upheld.

COMPLAINT

The complainant noted that Nicoventures was currently awaiting a licence from the MHRA for a nicotine replacement therapy (NRT) product. It had come to his/her attention, from a reliable source, that Nicoventures had set a call rate for health professionals for its sales teams, in this pre-licence period which he/she believed was against the Code in relation to marketing unlicensed products.

Nicoventures was asked to respond in relation to Clauses 2, 3.1, 9.1, 15.4 and 15.9 of the Code.

RESPONSE

Nicoventures explained that it had performed a thorough investigation and had not issued incentivised activity targets.

Nicoventures explained that it was awaiting a marketing authorization approval from the MHRA for its NRT product, Voke. It was therefore in the pre-licence stage for this product and operated within the guidance of Clause 3.1 of the Code (supplementary information). The only activity which the healthcare development managers (HDMs) were engaged in was that of advance notification of the product to those responsible for making policy decisions on budgets. The HDMs were not telling other health professionals about Voke.

Nicoventures noted that someone had complained to the MHRA earlier in the year and alleged that the company had sought meetings to promote an unlicensed product. Nicoventures provided evidence to the MHRA and the complaint was not upheld.

Nicoventures provided slides which described the HDM incentive scheme; the slides had been approved by the senior management team, certified and presented to the HDM team. The incentive scheme represented a maximum of 10% of their take home pay. The first part of the incentive scheme was based on identifying customers and

local guidance documents, as well as conducting budget holder meetings. The second part was based on a customer completed web-based quality questionnaire. The questions only related to influencing skills, interpersonal and team skills, planning and organisation and business acumen. The activities described in this incentive scheme were the same as the HDMs' objectives in this advance budget notification phase. This was important as the company wanted to stress the types of behaviour that it expected from the team.

The presentation expressly stated that there was no activity measure (call rate or other activity target) as a qualifier for, or as part of, the incentive scheme. Also the activity log for the HDM team showed that the call rate had been low.

At a meeting in July, the sales and marketing team conducted a strategic review of activity and it was clear that the effectiveness of the HDM team was severely hindered by various external parties who encouraged NHS officials to block access to the team. Thus the opportunity for telephone or face-to-face meetings with budget holders was significantly compromised.

As part of this review, the low level of activity within the team was discussed and levels of activity commonly achieved across the industry in the pre-licence and post-licence phase were considered. The regional business directors (RBDs) met with their HDM teams and passed on this information verbally and by email. Unfortunately these communications were not certified and referred to 'contact rates' and 'contact rate targets', despite the fact that it was made clear in the accompanying briefings that these were not incentivised target rates. Neither the objectives nor the incentive scheme were altered.

When the sales team joined in May 2013, Nicoventures expected the product licence to be granted later that year. The company recently learnt that the marketing authorization was unlikely to be granted until 2014.

No summary of product characteristics was available but it would be based on the reference product, the Nicorette inhalator. Nicoventures did not intend to immediately launch the product to prescribers or make it available to the NHS. The product launch would focus initially on consumer sales through pharmacy and retail channels. Consequently, advanced budgetary notification was appropriate for a subsequent NHS launch, and the company expected to focus the activity of its HDMs to pharmacy in the near future. The call rates described in the RBDs' slide deck clearly referred to this. Following receipt of the complaint and the subsequent investigation, an email to clarify the situation regarding objectives and the incentive scheme was sent on 15 October. However, the company had not had feedback from any of its HDMs that they misunderstood that the call rates communicated were formal objectives, incentivised or anything other than an indication of how it hoped activity would pick up in the coming months, given licence approval would make access more straightforward, albeit to a changing customer base. The company had also reminded the RBDs that all material communicating with the HDMs must be approved and certified.

Nicoventures remained vigilant that communication from its management team to the RBDs remained consistent with the Code and it denied breaches of Clauses 2, 9.1, 15.4, and 15.9.

The RBDs and HDMs all had significant experience in the pharmaceutical industry. A condition of joining the company was that they had all passed the ABPI representatives examination and their initial training with Nicoventures included a refresher course on the Code.

In response to a request from the case preparation manager to respond in relation to Clause 3.1 and call rates, Nicoventures reiterated that it did not issue incentivised activity targets for the HDMs. This would not have been appropriate during advance budgetary notification of the product. It was true that it asked the team to arrange advance notification meetings with those responsible for making policy decisions on budgets. At no time were the calls promotional in nature. The company also explained that the HDMs' effectiveness was severely hindered by external parties who encouraged NHS officials to block access to the team, meaning that the opportunity for telephone or face-to-face meetings with budgetary holders was significantly compromised. The HDM team was thus somewhat demoralised and the communications sent to it by the RBDs were intended to motivate and explain what might be possible to achieve once the marketing authorization had been granted and the team could talk to pharmacists. At no time were these illustrations of possible future activity reflected in the HDMs' objectives or their incentive scheme.

Nicoventures believed that the product met the requirements of Clause 3.1. It was a new type of NRT, designed to deliver nicotine in a similar way to a cigarette, and gave smokers the experience they wanted. Other inhaled nicotine products that looked and felt like a cigarette (e-cigarettes), were currently marketed under the General Product Safety Directive. The company anticipated considerable interest in a technology that met the quality, safety and efficacy standards expected of NRT. Nicoventures noted that the product would be the first e-cigarette-like product made in the UK to good manufacturing practice.

Nicoventures anticipated that the product could significantly change costs to the NHS and particularly to local authorities, who since April 2013 had had responsibility for local stop smoking services. It therefore considered that there was a need to provide advance information about the introduction of this new medicine to those responsible for making policy decisions on budgets.

National Institute for Health and Care Excellence (NICE) public health guidance 45, Tobacco: harm-reduction approaches to smoking, issued on 5 June 2013, set out recommendations to reduce the harm from smoking. These recommendations were intended to support and extend the reach of existing stop smoking services. They referred to long-term use

of nicotine-containing products by smokers who might not be able to stop smoking in one step, to those who did not want to give up nicotine or reduce the amount they smoked.

It was accepted that the prevalence of smoking in the UK had not dropped significantly over the last 6 years and that 85% of those who tried to stop smoking had failed to do so at one year. Anything that encouraged smokers to try and to continue to use NRT for as long as they needed it must be seen positively and the company believed that its product would make a significant contribution to this.

In market research conducted last year, in full alignment with the MHRA, its product demonstrated the potential to take market share from tobacco to a greater degree than the Nicorette Inhalator.

In the study, participants were issued a supply of test product (novel device with nicotine dose 0.22mg (low) or 0.45mg (medium)) or Nicorette Inhalator (15mg nicotine). Subjects completed a product market research questionnaire at baseline, and after 3 and 6 days of use (n=574), the data was fed into a market research model enabling modelling of expected market performance of the product and validation against a database of historically tested tobacco products. The study results showed that Voke would have a significant effect on the market and thus gave Nicoventures confidence to make further important manufacturing investment decisions. Nicoventures submitted that the introduction of Voke would increase NHS spending.

Further, the prevalence of smoking in the UK remained stubbornly at about 20% of the adult population. Whilst it was accepted that the best way to reduce the harm of smoking was to stop completely and in one step, for many smokers this could be difficult to achieve, especially for those who were highly dependent on nicotine.

Around two-thirds of smokers stated that they would like to quit or cut down. NICE now recommended that stop smoking advisers and health professionals should advise people to stop smoking in one go, but for those who were not ready or were unable to stop in one step, they should suggest considering a harm-reduction approach. This presented new ways for smokers to change their smoking behaviour, allowing more smokers to be supported by NHS stop smoking services and other healthcare providers in the UK. This would inevitably lead to increased footfall into services and therefore an increased uptake of licensed nicotine-containing products.

Stop smoking services might see the product as a useful addition to the products which could be offered to smokers. Recommendation 6 of the NICE guidance advised those supplying nicotine-containing products to: 'Offer all types of licensed nicotine-containing products to people who smoke, as part of a harm-reduction strategy (either singly or in combination). Take into account their preference and level of dependence'.

A product that smokers wished to use would encourage compliance, helping stop smoking services to meet their targets. Prescription of NRT in line with NICE guidance would help to meet government targets to address health inequality. It was important that budget holders knew about the guidance and the impact a product like Voke could have on their budgets.

To achieve this, Nicoventures had employed a team of HDMs. These individuals were highly experienced, had passed the ABPI examination for representatives and had received refresher training on the importance of complying with Clause 3.1 of the Code, Advance Notification of New Products. They made appointments with local budget holders and policy decision makers, including directors of public health, to discuss the potential impact of tobacco harm reduction and the product on their budgets, using a budgetary implications presentation and a budget impact model (copies were provided). The information contained a brief description of the product in the form of a single slide showing it as a non-branded picture, and further limited factual information about it was only provided on request.

The company stated that it had been fastidious in meeting only budget holders. Its small team of HDMs had provided a suitable background to that field, the NICE guidance and the budgetary impact of introducing the new product.

In response to a request from the Panel for more information, Nicoventures explained that as the complainant referred to a sales team it had used this term in its response. However this team, which had always been referred to internally as a healthcare development team, had always had one objective in the pre-licence phase ie advanced budgetary notification to only those responsible for making NHS strategic and policy decisions on budgets.

The healthcare development team consisted of a number of HDMs managed by 2 RBDs, all of whom were employed by a contract organisation. Nicoventures stated that it used the term 'sales and marketing team' to refer to the team responsible for sales and marketing. Nicoventures provided an organogram to show the relationships between the different personnel.

Nicoventures also provided copies of job descriptions for the HDMs and RBDs and noted that their roles were clearly divided into two phases: 1) pre-licence advanced budgetary notification and 2) post-licence education, product launch and promotion. It had always been intended that the HDMs and RBDs would ultimately become the contract health professional salesforce/business managers, managed by a contract organisation after grant of the product licence. The expectation was for the educational/promotional activity to focus on retail pharmacy after licence grant and then extend to relevant NHS personnel when the product was launched to the NHS.

Nicoventures stated that it had been acutely aware of the scrutiny it would be under given its parent

company, as it sought to build trust in the tobacco harm reduction space. It had therefore been careful to recruit experienced pharmaceutical professionals. The constant message from the top to all employees, especially this important customer-facing contract team, had been that they must operate conservatively and to the highest standards. Nicoventures noted the difficulties they faced in gaining legitimate access to the NHS (following a well-orchestrated external campaign). Despite this, and the natural frustration it caused among such high performing, committed individuals, the company has repeatedly made it clear that its reputation for professionalism came first and that 'call rates' were not something for which they would be incentivised 'pre-licence'.

PANEL RULING

The Panel noted that the complainant had alleged that, by setting call rates for its field force (HDMs) to talk to health professionals about its unlicensed medicine, Nicoventures had breached the Code.

The Panel noted that Nicoventures was awaiting a marketing authorization for its nicotine-containing product, Voke. The supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes stated that NHS organisations needed to be told in advance about medicines which, once marketed, would significantly affect their budgets. The information provided had to be limited to that sufficient to provide a succinct account of the product's properties and directed to those responsible for making policy decisions on budgets rather than those expected to prescribe. Nicoventures had recruited a team of HDMs to provide advance notification of its new product.

The Panel noted a slide included in the marketing strategy presentation for the HDM regional meeting which was headed 'Nicoventures Incentive Scheme'. Under a sub-heading of 'Part 1 (GAP analysis): Completion of the following parameters' was listed 'Identification of customers', 'Identification of local guidance documents' and 'Conducting Budget Holder Meetings'. In that regard the Panel noted that a component of the HDMs incentive scheme was linked to conducting meetings. On the left-hand side of the slide, however, it was stated 'No activity measure as a qualifier' In the Panel's view it was not necessarily unacceptable to include meetings in the HDMs' incentive scheme. The Code recognised that advance notification was appropriate in certain situations; there was no requirement that such information could only be provided reactively.

The Panel considered that as there was no prohibition in the Code with regard to setting call rates for the delivery of advance notification to health professionals, to do so did not, in itself, amount to promotion of a product prior to the grant of a marketing authorization. On the narrow grounds of the complaint, no breach of Clause 3.1 was ruled. The Panel did not consider that there was any evidence to show that the frequency, time and duration of calls made by the HDMs had caused inconvenience. No breach of Clause 15.4 was ruled. With regard to call rates the Panel did not consider that the HDMs' briefing material advocated either directly or indirectly any course of action which was likely to lead to a breach of the Code. No breach of Clause 15.9 was ruled.

The Panel noted its ruling above and did not consider that high standards had not been maintained. No breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

Complaint received **16 September 2013**

Case completed **21 January 2014**