EX-EMPLOYEE v NAPP

Flutiform promotional practices

An ex representative, previously employed by Napp through a third party agency, complained about various promotional practices within Napp.

Napp's detailed response to each allegation is given below.

The complainant stated that one of his key performance indicators (KPIs) was to get ten target GP practices to 'switch' a percentage of asthma patients on GlaxoSmithKline's Seretide Evohaler (salmeterol plus fluticasone) to the equivalent doses of Napp's Flutiform metered dose inhaler (MDI) within a specified timeframe. The complainant noted, however, that the prescribing particulars (age range and indications) of Seretide Evohaler and Flutiform were different and so the two were not wholly interchangeable. Further, the percentage switch conversion was unrealistic as there were no financial incentive schemes in named local clinical commissioning groups (CCGs) to switch. This, together with rebates from GlaxoSmithKline on Seretide Evohaler and from other manufacturers on other inhalers meant that some of the cost savings claimed by Napp for a switch to Flutiform were inaccurate. The complainant stated that he was under significant and sustained pressure to deliver on business outcomes. The complainant was further concerned that emailing surgery prescribing data could potentially breach data protection.

The complainant noted that Napp's marketing material did not refer to asthma patients prescribed Seretide Evohaler who were also diagnosed with asthma-chronic obstructive pulmonary disease (COPD) overlap syndrome (ACOS); Flutiform was not licensed for COPD. Napp's marketing message of a simple switch was misleading. Even in Napp's own marketing material there were a number of differences between Seretide Evohaler and Flutiform, which meant that the medicines were not like-for-like formulations. A simple switch should not be taken as like-for-like dose changes, but the actual process of making changes which was rather more involved and required firm commitment from the practice.

The complainant stated that practices could do the switches themselves or via one of two services offered by Napp which were seen as independent non-promotional services but were set up to switch inhaler medicines to Flutiform. The complainant stated that he was briefed about this service via Napp's intranet site but that specific in-house, face-to-face training and validation were lacking. The complainant also stated that he did not know when these service were being provided within his target surgeries and that he could order non-promotional materials despite not having been trained. The complainant alleged that, in pursuit of sales, compliance towards switches and Napp's briefing on switches from his manager (the area business manager (ABM)) was very lax. As Napp was driving switches, the non-promotional service should not have been used as the introduction was linked to Flutiform as a commitment from the customer to make changes through quality outcomes framework (QOF) and patient review in the first call and to then sign up to the service in the second call.

The Panel noted that the parties' accounts differed; it was difficult in such circumstances to determine precisely what had happened. A judgement had to be made on the available evidence whilst noting that the complainant bore the burden of proof and had to establish his case on the balance of probabilities.

The Panel noted that the complainant's concern was that the percentage switch conversion from Seretide Evohaler to Flutiform, as set out in his KPIs, was unrealistic. The Panel noted that it appeared that the KPIs had been agreed by the complainant and that he was required to achieve a stated switch success rate within ten target GP practices within 6-8 months. It was stated that a switch should be 50% or more of a surgery's Seretide Evohaler marketshare to the equivalent dose of Flutiform. The Panel considered that the absence of incentive schemes in the CCGs did not necessarily mean that a switch would be unrealistic. Much would depend on whether health professionals considered that the benefits of a switch outweighed the work required to action it. The Panel did not consider that the complainant had proven that, on the balance of probabilities, the percentage switch was unrealistic for the reasons alleged. Nor that Napp in setting this KPI advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. No breach of the Code was ruled.

The Panel further noted the complainant's concern that there were rebates in place in the three named CCGs for Seretide Evohaler and another inhaler Sirdupla and therefore the cost saving figures in the leavepiece concerning medicines optimisation for one of the named CCGs were inaccurate and misleading. The Panel noted Napp's submission that the leavepiece compared NHS list prices and national prescribing data to ensure licensed age ranges were taken into account when calculating the potential cost savings. The Panel noted Napp's submission that the complainant had been briefed on the leavepiece and confirmed that he understood how to use it. The Panel considered that although discounts etc might make it possible to buy medicines at less than the NHS list price, it was not unreasonable for companies to base price comparisons on the NHS list price when this was made clear. The Panel did not consider that the complainant had proven that, on the balance of

probabilities, the leavepiece was misleading in that regard. On the narrow grounds alleged the Panel ruled no breach of the Code.

The Panel reviewed two emails provided by the complainant in support of his allegation that he was under pressure to get practices to switch and the allegation that discussing surgery prescribing data and patient switches in emails could potentially breach data protection laws. The Panel noted Napp's submission that the content of the first email displayed the manager's concern that the likelihood of a switch in the named GP practice was low thus calling into question the complainant's sales abilities. The second email predated the first and provided details of a business review held between the complainant and his ABM. The email highlighted the complainant's progress against his mutually agreed KPIs.

The Panel did not consider that it was necessarily unacceptable for ABMs to require weekly progress updates provided that such did not contravene the requirements of the Code. The Panel did not consider that the complainant had proven that he had been under sustained pressure from the ABM to deliver on business outcomes that did not comply with the Code as alleged. No breach of the Code was ruled. Nor had the complainant proved that that the ABM requesting weekly updates would advocate directly or indirectly any course of action that would be likely to breach the Code. No breach of the Code was ruled.

The Panel noted Napp's submission that the emails provided by the complainant did not contain any patient specific data and the information sought was anonymous in nature. The Panel further noted Napp's submission that to the extent that the emails mentioned individual health professionals, this publicly available information was used for legitimate business purposes and was subject to appropriate safeguards. The Panel was concerned about activities in relation to the Code. It was not for the Panel to determine whether Napp's activities were in line with data protection requirements *per se*.

Clause 1.11, however, stated that companies must comply with all applicable codes, laws and regulations to which they were subject. This clause had not been raised and the complainant had not provided evidence that the companies had been found in breach of data protection requirements. Given the circumstances the Panel therefore considered that there was no evidence that high standards had not been maintained and it ruled accordingly.

With regard to the use of the medicine for asthma overlap syndrome (AOS) and COPD as Flutiform was not licensed for COPD, the Panel noted Seretide Evohaler's SPC and Napp's submission that Seretide Evohaler was not licensed to treat ACOS or COPD and therefore there was no need for such a consideration within its materials which referred to switching including the leavepieces. Seretide Accuhaler was licensed to treat both asthma and COPD. The Panel did not consider that the material was misleading in that regard and no breach of the Code was ruled.

The Panel noted that the complainant provided the incomplete front page of a document which stated 'A simple switch to Flutiform Real Difference' and an extract from another leavepiece which included a table highlighting differences between Seretide Evohaler and Flutiform. The Panel noted the complainant's allegation that describing the switch as 'simple' was misleading as making changes was more involved and required significant time investment from practices. The Panel noted that under the Code, a company could promote a simple switch from one product to another but could not assist in implementing that switch. The Panel noted that it would take time to review patients who potentially could be switched but considered that the reference to 'a simple switch' in the supplementary information to the Code referred to switching from one medicine to another in relevant patients. The Panel noted that the complete document provided by Napp was titled 'A simple switch to Flutiform can make a real difference to your patients'. The leavepiece discussed some of the features of Flutiform followed by study results from patients switched from Seretide Evohaler to Flutiform.

The Panel further noted Napp's submission that 'simple' was used to describe the switch from Seretide Evohaler to Flutiform as both products were similarly licensed for asthma maintenance and differences in licensed age ranges were clearly stated; both were MDI's; and both contained the same inhaled corticosteroid, so no steroid dose conversion was necessary.

The Panel noted that the leavepiece referred to the licensed indication of Flutiform including the age range for the various strengths and that it was for patients 12 years and older (low and medium strengths) and adults (all dosage strengths). The leavepiece stated that patients previously controlled on Seretide Evohaler 250mcg could be switched to Flutiform 250mcg and maintain good asthma control. A bullet point below in less prominent font stated that this was based on a 12-week study in 225 adult asthma patients. The leavepiece did not include the licensed indication for Seretide including the age range or the differences in licensed age ranges between Flutiform and Seretide as stated by Napp. The Panel queried why the leavepiece did not state that patients aged 5 to 12 could not be switched from Seretide Evohaler to Flutiform. The second leavepiece referred to by the complainant, entitled 'Do you have a medicines optimisation plan to switch asthma patients from Seretide Evohaler? Why choose Flutiform', included the claim 'A simple switch can make a real difference' and asked the reader what was important to them when switching patients from Seretide Evohaler to Flutiform. The leavepiece compared various features of Flutiform, Seretide Evohaler and Fostair including change in steroid from Seretide Evohaler, patient-facing dose indicator and refrigeration required prior to dispensing. Page 3 compared Flutiform and Fostair

in terms of dose delivery and steroid percentage at the lowest daily dose. Whilst the leavepiece stated the licensed indication of Flutiform including the age range for the various strengths, it did not refer to the licensed indications of Seretide or Fostair including the age range. There would be patients who could simply be changed from Seretide to Flutiform. Notwithstanding its comments about the two leavepieces above, the Panel did not consider that the complainant had proved that describing the switch in the leavepiece as simple was misleading due to the time investment required by surgeries. Based on this very narrow allegation the Panel ruled no breach of the Code.

The Panel noted the complainant's concerns about the services offered by Napp to assist surgeries to switch from Seretide Evohaler to Flutiform. The Panel did not consider that there was any evidence before it to demonstrate that the service as implemented was included in individual sales targets or was only offered where a switch was guaranteed as alleged. No breaches of the Code were ruled.

The Panel considered the service in relation to the allegations about the promotional materials which focussed on switching patients to Flutiform. The Panel noted Napp's submission that account managers, including the complainant, were only allowed to introduce the service briefly and in accordance with the approved briefing. In October 2016, the complainant received live, 1 hour, on-line training on the new pharmacist-led review service and a follow-up briefing document to further clarify the process which specified the dos and don'ts for account managers in terms of non-promotional vs promotional calls and to which was attached the service introduction document. Napp noted that the complainant acknowledged that he had read and understood the briefing document. The Q&A stated that once a therapeutic review was in progress in a practice, account managers were not allowed to discuss the asthma review service with any of the health professionals in that practice. The briefing included relevant requirements from the Code. The Panel noted Napp's submission that the complainant was not informed about services within his target surgeries because there had been none whilst he was employed. The Panel further noted that the complainant had been instructed not to introduce the therapy review service.

The Panel noted that a briefing document, the training slides for account managers and the material provided by the complainant set out what discussions could take place in a promotional call and a non-promotional call. The promotional call flow diagram covered situations for customers who had agreed to switch either with no assistance or where assistance was requested. In both situations no therapeutic review would be offered. The flow diagram for the non-promotional call whereby the health professional had an interest in therapeutic review, the service introduction document was to be used and the practice referred to the ABM/ healthcare development manager (HDM). The Panel did not consider the training materials were sufficiently clear given that the main promotional message was for a switch to take place. In addition, leavepieces promoting the switch were to be left at the end of the call. There was no flow diagram or other instructions in the training material for the situation when the service was briefly introduced during a promotional call. It was not clear from the briefing documents for account managers that if a practice had agreed to switch, the service could not be offered in that practice even in a subsequent non-promotional call by the account manager or an ABM/HDM. However, this did not necessarily mean that the therapy review service offered by Napp was linked to the promotion of Flutiform as alleged. The Panel noted its comments and rulings above and although concerned about the relationship between the promotional messages about switching and the service which provided resource to change patients' medication including to Napp's product Flutiform, it did not consider that the complainant had shown on the balance of probabilities that the arrangements failed to meet the requirements of the Code. The Panel therefore ruled no breach of the Code. The Panel did not consider that the complainant had provided evidence that in pursuit of sales, Napp's compliance and briefing on switches from the ABM were very lax as alleged. The Panel consequently ruled no breach of the Code including Clause 2.

The complainant noted that he was pressurised to increase sales and call and contact rate via emails from Napp and the contract agency but that these communications did not refer to the Code regarding solicited/unsolicited and the frequency of calling and remaining Code compliant.

The Panel noted that the email provided by the complainant was sent by the third party agency and it discussed the complainant's progress in terms of improvement in his call rates and an increase in the number of 1:1 appointments confirmed. The Panel noted Napp's submission that the complainant was urged to increase his activity; he had only seen around one target GP surgery every 5 weeks. The Panel considered that whilst it might be preferable to refer to the requirements of the Code whenever calls or contacts were discussed with representatives, given the complainant's call rates there was no evidence to show that Napp, in encouraging him to increase his activity, had advocated either directly or indirectly any course of action which was likely to breach the Code. The Panel noted Napp's submission that all of its account managers were trained on the Code including its requirements regarding call and contact rates. The Panel ruled no breach of the Code. There was no evidence that Napp had failed to maintain high standards in this regard nor that the company had brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel ruled no breach of the Code including of Clause 2.

The complainant noted that Napp organised an external speaker through a series of meetings as a tactic to access health professionals at and after the meeting, however Napp did not provide any briefing about whether the speaker was only to be offered at nurse meetings and not GP meetings. The complainant provided an email which showed that his ABM was reluctant to sponsor a meeting for a

particular group of GPs because previous experience showed that they were 'not of particular value'. The complainant considered his AMB's comments derogatory and unprofessional. The complainant further stated that the contract agency suggested in its communication with him that such a meeting was linked to a return on investment. The complainant was not sure if Napp was copied into this communication. The contract agency briefing to the complainant was simple and in breach with no written reference to the Code to protect itself as an organisation.

The Panel noted that Napp did not comment on the complainant's allegation that Napp had used the promotional meetings as a tactic to gain access to health professionals at and after the meetings. The Panel considered that it was not necessarily unacceptable for meetings to be a means of interacting with health professionals. Noting the complete absence of evidence, the Panel considered that the complainant had failed to show that there had been a breach of the Code with regard to the use of the meetings and so it ruled no breach of the Code including Clause 2. In its response Napp had cited a clause of the Code which was not relevant to the matter; no breach of that clause was ruled.

The Panel did not consider that in referring to a group of GP's as being 'not of particular value' the ABM had been derogatory as alleged; it was not necessarily unacceptable for a company to decide which health professionals to promote to based on a return of investment provided that requirements of the Code were met. The Panel did not consider that Napp had failed to maintain high standards; no breach of the Code was ruled.

An ex-employee, previously employed via a third party contract agency by Napp Pharmaceuticals Limited, complained about various practices within Napp.

The complaint included concerns about the promotion of Flutiform (fluticasone propionate/ formoterol). Flutiform indications included the regular treatment of asthma where a combination product (an inhaled corticosteroid (ICS) and a long action B2 agonist (LABA)) was appropriate. Flutiform 50mcg fluticasone/5mcg formoterol and Flutiform 125mcg fluticasone/5mcg formoterol were indicated in adults and adolescents aged 12 years and above. Flutiform 250mcg fluticasone/10mcg formoterol was indicated in adults only.

When writing to Napp, attention was drawn to the requirements of Clauses 2, 7.2, 7.4, 9.1, 15.9 and 19.2. Attention was also drawn to the supplementary information to Clause 15.4.

Napp noted that the complainant had his sales role contract terminated early due to unacceptable performance. Napp added that the complainant had passed the ABPI representatives examination some years ago and was employed by Napp in an area where he had worked previously and would thus be expected to know the local NHS environment and health professionals. With a number of years' experience selling, Napp considered that the complainant should have clearly known about the role of a primary care representative and the Code.

1 Switches to Flutiform

COMPLAINT

The complainant stated that one of his key performance indicators (KPIs) set by his area business manager (ABM) was to get ten target GP practices to 'switch' a percentage of asthma patients on GlaxoSmithKline's Seretide Evohaler (metered dose inhaler (MDI)) (salmeterol plus fluticasone) to the equivalent doses of Flutiform also an (MDI) within a specified timeframe.

Seretide Evohaler and Flutiform differed in their licensed indications and age range and so a 100% switch conversion could not be achieved which was referenced in Napp's leavepiece. Some of the practices that were chosen were not overspent on their respiratory prescribing budgets, which was just recently known to the complainant. The complainant stated that the percentage switch conversion was very unrealistic as there were no specific incentive schemes in place in three local, named clinical commissioning groups (CCG) to switch exclusively to Flutiform. The complainant stated that in addition GlaxoSmithKline gave a stated rebate in those three CCGs with Seretide Evohaler which meant that one of the named CCGs would only potentially save £114,396 by changing to Flutiform and not £142,995 as misleadingly stated in the leavepiece. The complainant believed that there was also a rebate in place for Sirdupla (salmeterol plus fluticasone, marketed by Generics UK) and the cost savings of Flutiform vs Sirdupla were also inaccurate. The complainant stated that the pressure from his ABM to convince practices was significant as he had to email his progress within his target practices weekly. The complainant referred to the sustained pressure to deliver on business outcomes and provided two in-house emails. The complainant further stated that emailing surgery prescribing data and patient switches could potentially breach data protection which was not noted and corrected by the ABM.

The complainant stated that Napp's marketing communication was to switch asthma patients from Seretide Evohaler to Flutiform, however, no reference was made to differentiate those asthma patients prescribed Seretide Evohaler who were also diagnosed with asthma-chronic obstructive pulmonary disease (COPD) overlap syndrome (ACOS); Flutiform was not licensed for COPD. The complainant stated that Napp's marketing message of a simple switch was misleading as administrative and/or clinic based reviews still required the surgery to invest significant time to audit appropriate patients, exclude those not within the licensed indications of Seretide Evohaler, explain the change, check inhaler technique and inform local community pharmacists to run down stocks of Seretide Evohaler. Even in Napp's own marketing communication, there were a number of differences between Seretide Evohaler and Flutiform, which meant that the medicines were not like-for-like formulations. A simple switch should not be taken

as like-for-like dose changes, but the actual process of making changes which was rather more involved and required firm commitment from the practice.

The complainant stated that switches could be achieved either by influencing practices to make the switch in-house and/or introducing a nurse (ORCA) and/or a pharmacist service, to practices if resource was required, which was seen as an independent non-promotional service but was set up in such a way to use this service to switch inhaler medicines to Flutiform. The complainant stated that he was briefed about this service via Napp's intranet site but received no specific in-house, face-to-face training from Napp and no validation of a promotional call and a non-promotional service call with customers. The complainant also stated that he was not informed when these service nurses and pharmacists would be present within his target surgeries. He could order non-promotional materials, despite not having been trained by the training department and ABM. The complainant alleged that, in pursuit of sales, compliance towards switches and Napp's briefing on switches from the ABM was very lax during discussions in the field. As Napp was driving business outcomes for switches, the non-promotional service should not have been used as the introduction was linked to Flutiform as a commitment from the customer to make changes through quality outcomes framework (QOF) and patient review in the first call and to then sign up to the service in the second call.

RESPONSE

Napp noted the complainant's statement that one of his KPIs set by his ABM/Napp was to get 10 target GP practices to 'switch' a percentage of asthma patients on repeats from Seretide Evohaler to the equivalent doses of Flutiform within a specified time frame. In that regard, Napp noted that the complainant's KPI document referred to his mutually agreed KPIs. For Flutiform sales, the document referred to achieving firstly, a stated switch success rate within 10 identified GP surgeries selected jointly with his ABM within 6-8 months of his 12 month contract. It was also stated that 'A switch success should be 50% or more of the Seretide Evohaler (an asthma inhaler) market share'. Napp stated that this was clearly not a 100% switch as alleged.

The second point of the KPI document was about the complainant calling on 80% (ie coverage) of at least 1 decision maker (GP, practice nurse or practice manager) in these top 10 GP surgeries within 4 months of being trained by to sell Flutiform in asthma. Napp stated that it would return to this point when addressing point 2 of the complaint concerning call and contact rate below.

Napp submitted that the complainant was almost correct in that there was one difference between the Seretide Evohaler and Flutiform in that Flutiform was not licensed for the treatment of asthma patients below the age of 12 years, whereas Seretide Evohaler was licensed for children from 5 years and up. Napp noted that a recently introduced cost-saving generic alternative to Seretide Evohaler, Sirdupla, could be a switch choice as part of medicines optimisation by a CCG. Sirdupla was only licensed for the treatment of asthma patients aged 18 years or over. The leavepiece provided by the complainant, concerned medicines optimisation for a named CCG, ie one of the three CCGs identified within his Flutiform KPI. Scrutiny of this document clearly highlighted in several areas the age differences when comparing Seretide Evohaler with Sirdupla or Flutiform as potential cost-saving asthma inhalers. Indeed, boxed text at the top of a page stated 'This document outlines the points to consider when discussing Flutiform or Sirdupla as alternatives to Seretide Evohaler for patients with asthma across [a named] CCG'. Also within this box the first bullet point stated in a balanced and factual way that 'Moving *appropriate* patients onto either Flutiform or Sirdupla can produce significant cost savings' (emphasis added). The use of 'appropriate' referred to patients identified within the licensed indications of each of the medicines. This contrasted markedly with the complainant's assertion that the document was all about 100% switch conversion from Seretide Evohaler to Flutiform MDI. The first table compared Seretide Evohaler with Sirdupla and Flutiform. The middle row of the table highlighted the age comparisons in the licensed indications for each of the 3 medicines: both Seretide Evohaler and Flutiform had a 'medium strength licensed for children > 12 years', whereas the Sirdupla column stated with a red cross to indicate that it was not licensed for this age range, and stated in the table that it was for 'adults > 18 years'. This fact was also reinforced in the orange box to the right of the middle of the page as it posed the question 'If switching to Sirdupla rather than Flutiform what about patients aged 12-17?'.

The second table of the leavepiece was entitled 'Potential annual cost savings in [a named] CCG'. Cost calculation information was provided to highlight how the doses and age ranges within the licensed indications for the three medicines was calculated. The final column provided again the numbers of appropriate patients for switch to Flutiform or Sirdupla. This did not imply or mislead to draw a conclusion that Napp advocated a 100% switch to Flutiform and for all ages. The cost calculation information explained that not all ages could be switched from Seretide Evohaler to Sirdupla because of the doses and licensed age range of >18 years for Sirdupla. The second bullet point of the cost calculation information stated that 'The number of Seretide Evohaler patients appropriate for Flutiform had been modelled from prescribing data using national patient data *to account for the licensed indication and age range for Flutiform*' (emphasis added). A bold orange background box further emphasised the licensed indication of Flutiform running along the bottom of the page but in bold clear font of the text 'flutiform is licensed for asthma maintenance therapy for patients 12 years and older) low and medium strengths), adults (all strengths)'. Napp firmly disagreed with the complainant that this material advocated a 100% switch from Seretide Evohaler to Flutiform. Napp submitted that the information, claims and comparisons within the

leavepiece were accurate, balanced, fair, objective and unambiguous for the reasons provided. They did not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. The information and comparisons were substantiated by the accompanying references within the material. Furthermore, a health professional could just as easily decide to switch patients to Sirdupla rather than Flutiform. Napp asserted that the promotion of Flutiform relevant to the complainant's first allegation was not in breach of Clauses 7.2 or 7.4. High standards had been maintained and thus Napp denied a breach of Clause 9.1. Napp submitted that the complainant was briefed on the material by his manager and his mentor and had confirmed that he understood how to use it appropriately and with the right customers (ie GP respiratory/prescribing leads, not necessarily nurses). Napp therefore denied a breach of Clause 15.9. Napp submitted that the briefing document offered the complainant direct contact with a Napp market access manager or a brand assistant if he had any questions. Napp was not aware that the complainant had contacted either of these two people or his manager to discuss any concerns. Napp noted that the last bullet point of the briefing document in the 'Actions' section stated 'Please make sure you are clear on the data and its assumptions before using it with your customers'. Napp queried why the complainant did not raise any issues he had with Napp whilst contracted to it?

Napp noted the rebates stated by the complainant but queried how and from where such data had been obtained given that rebate percentages were confidential. Although price rebates might be offered to local CCGs, they were confidential contractual arrangements between the pharmaceutical company and the NHS payors and were therefore not publicly available. It would be inappropriate for Napp to speculate on the potential rebate percentages offered by its competitors, as this might be inaccurate, misleading and therefore not a fair comparison in breach Clauses 7.2 and 7.4. Hence the leavepiece used to compare prices had been modelled on national prescribing data to ensure licensed age ranges were taken into account. The table was clearly labelled as such and NHS list prices were used to ensure accuracy and fair representation of the published prices, upholding Clauses 7.2, 7.4 and 9.1.

Napp submitted that it was normal for business managers to set clear expectations and put good communications in place with their reports. The complainant had been supported by his manager with regular email correspondence, monthly face-to-face meetings and field visits. The complainant's ABM had, *inter alia*, stated when interviewed by Napp and the senior compliance manager that as the complainant was new in the role it was not unreasonable to suggest weekly reports if possible. The ABM, however, reported concerns about the quality of that feedback (details were provided).

Napp noted that the complainant was allocated a fellow representative as a mentor to provide help, advice and support. Such contacts would also highlight areas for development or improvement especially if KPIs were not being met or selling methods were inappropriate. It was therefore surprising that the complainant felt under significant pressure to do his job which was to sell in a responsible, ethical and professional manner. The complainant had provided two example emails to highlight 'sustained pressure to deliver on business outcomes'. One was a follow-up email from his manager after accompanying him to a GP practice lunchtime meeting. Within the email it was the complainant who was quoted by his manager in paragraph 2: 'I have a lunch meeting at the practice on [date] and [a named doctor] will tell me when in April and how many Seretide Evohaler patients switched to Flutiform'. Such information would form part of the agreed KPI that a successful switch would be at least 50% of the surgery's Seretide Evohaler market share – which was publicly available non-confidential information. Napp fundamentally disagreed that the emails relied upon by the complainant were in breach of data protection legislation. In particular, the emails did not contain any specific data about individual identifiable patients and the information sought was entirely anonymous in nature. To the extent that the emails mentioned individual health professionals, this information was a matter of public record and was being used by Napp for entirely legitimate business purposes and was subject to appropriate safeguards. Napp therefore refuted any breach of data protection for these reasons, and considered that it had maintained high standards consistent with Clause 9.1. It was also clear from the contents of the email from the analysis of the complainant's manager that the likelihood of switch occurring in this practice was low, calling into question the complainant's sales abilities. Finally, the email highlighted the complainant's selling skills by suggesting what questions he should ask the GP. It was therefore not surprising that the complainant's manager wished to be updated and importantly the email concluded with a closing sentence which stated 'You did say that you agreed with all of these points, please do let me know your plans for moving this forward'. If the complainant agreed, then Napp now concluded that he had since changed his opinion and provided it as an example of sustained pressure as subsequent events unfolded and he lost his job.

Turning to the second email, this was dated 10 days earlier than the email discussed above. The email was from the complainant's manager to provide written details of a business review meeting held 3 days earlier. The email first discussed the complainant's progress against his mutually agreed KPIs 5.5 months (22 weeks) after he had begun selling for Napp. Out of 30 GP surgeries (accounts) the complainant had only managed to see four ie around 1 surgery every 5 weeks.

The second email referred to practice level data of patients switching. This information would form part of the agreed KPI that a successful switch would be at least 50% of the surgery's Seretide Evohaler market share – which was publicly available non-confidential information.

Napp submitted that the complainant was factually incorrect in that neither Seretide Evohaler nor Flutiform were licensed to treat ACOS or COPD.

There was therefore no need for such a consideration within its materials. It was actually Seretide Accuhaler, a dry powder inhaler, that was licensed to treat both asthma and COPD. Napp submitted that it was aligned with the supplementary information to Clause 19.1 in promoting a simple switch from Seretide Evohaler to Flutiform in appropriate asthma patients. Napp also did not pay for such switches either directly or indirectly. Documents provided by the complainant had been extracted from complete documents, and so were incomplete and out of context. Napp provided copies of the complete documents and briefing documents. One document was entitled 'A simple switch to Flutiform'. The switch to Flutiform from Seretide Evohaler could be considered simple as both products:

- had very similar licensed indications for asthma maintenance therapy (Seretide had a paediatric licence, whereas Flutiform was for 12 years and older).
- any differences in licensed age ranges were clearly stated.
- in all Flutiform promotional materials the therapeutic indication was stated in the prescribing information and COPD/ACOS were never mentioned. Napp only promoted Flutiform in accordance with the licensed indication.
- were pressurised aerosol metered dose inhalers (MDIs) (some inhalers were dry powder devices requiring a different inhalation technique)
- contained the same inhaled corticosteroid, so no steroid dose conversion was necessary, unlike other asthma inhalers, eg Fostair (formoterol fumarate/beclometasone dipropionate marketed by Chiesi).

Napp submitted that a leavepiece (ref UK/FLUT-16007), promoted a switch to Flutiform and included the licensed indication, plume data and data from Kemppinen *et al* (2016). Notably, when discussing the results of Kemppinen *et al* on page 3 of the leavepiece, it was clearly stated that patients who changed treatment from Seretide Evohaler to Flutiform were controlled asthma patients. This statement had been included to ensure the nature of the patients in the study was clear to health professionals to allow for informed clinical decisions and ensure patient safety was not jeopardised.

Any switch between medicines required administrative and practical effort on the part of the health professionals. The statement 'A simple switch' was intended to reinforce the similarities between the products which enabled a change of medicine to be as simple as the health professional chose to do so. It was also in line with the Code (Clause 19.1, supplementary information) which stated that 'it would be acceptable for a company to promote a simple switch from one product to another'. Napp did not facilitate the switch as implementing this change was the clinical decision of the health professional. The complainant failed to be specific when presenting his arguments about an extract from a full leavepiece (ref UK/FLUT-16063a) about the differences between Flutiform and Seretide Evohaler. The table highlighted that Flutiform had a different long-acting beta agonist (formoterol) and a colour coded, patient facing dose counter. Napp submitted that these did not lead to a conclusion that a switch from Seretide Evohaler to Flutiform was complicated. Napp noted the complainant's comments about the nurse (ORCA) and/or the pharmacist service and explained that whilst the complainant worked for Napp there were no therapy review services undertaken in the business region in which he was employed. The complainant confused the promotion of switch services with the non-promotional therapy review service that Napp provided as a service to medicine. Napp strongly refuted the assertion that its therapy review service was actually a switch activity which would be a clear and serious breach of the Code. Napp noted that in Case AUTH/2808/12/15 the full details of the nurse-led ORCA therapy review service were scrutinised and the service was not found to be a promotional activity. Napp also provided full and complete details of the pharmacist-led asthma therapy review service including the criteria for selecting practices. The service was offered through a third party. Napp used two providers because feedback showed that some GP practices preferred therapy reviews to be undertaken by nurses whilst others preferred them to be led by a pharmacist. Both therapy review services were designed, organised and conducted in the same way, differing only by the use of either pharmacists or nurses to deliver the service.

Napp did not monitor any sales uplift in areas where the pharmacist-led or ORCA therapy review services had been conducted. Neither were representatives' bonuses based on Interface service to the NHS. A senior scientific advisor oversaw the service, as this was a non-promotional role and sat within the medical department, and had regular contact with the Interface head of clinical services, along with provision of a management report to discuss any operational issues.

Napp submitted that the sales teams, including their managers, did not have access to the Interface client reporting metrics as this was a non-promotional activity. The report was discussed within the medical and Code compliance department which allowed Napp to ensure with Interface that it offered the service in accordance to the provision of medical and educational goods and services (MEGS) as set out in Clause 19.2.

Napp set sales targets but pharmacist-led asthma therapy reviews were not included in the calculation that it used to determine what growth a region could deliver.

The number of therapeutic reviews by region/area were not included at any point in the calculation of the targets and were not monitored in relation to measuring success against that target. Napp did not include any planned or future Interface asthma reviews in the calculations used to determine the sales targets and Napp did not incentivise staff based on these reviews and no individual sales person's target was affected by the asthma reviews.

Napp submitted that the complainant's statement that he was briefed on the pharmacist-led review

service via Napp's intranet site but received no specific in-house, face-to-face training from Napp and no validation of a promotional call and non-promotional service call with customers was incorrect. Account managers, including the complainant, were only allowed to introduce the service briefly as allowed by the Code and in accordance with the briefing document (ref UK/RES-16082c). Napp submitted that the complainant received (along with other account managers) a live 1 hour, on-line WebEx training on the new pharmacist-led review service and process from. This was a 'virtual' face-to-face training to avoid field-based account manager needing to travel to head office. The training included a Q&A session and a follow-up briefing document to further clarify the process (ref UK/RES-16082c) to which was attached the service introduction document. Napp noted that the complainant acknowledged that he had read and understood this briefing document.

The briefing document (ref UK/RES-16082c) specified the dos and don'ts for account managers in terms of non-promotional vs promotional calls as represented by the flow diagram on page 2. The Q&A section of this document specified that once a therapeutic review was in progress in a practice, account managers were not allowed to discuss the asthma review service with any of the health professionals in that practice. It also detailed the requirements of the therapeutic review service in accordance with the Code (MEGS and therapeutic review).

Napp's ABMs and healthcare development managers (HDMs) were the only people allowed to discuss the therapeutic review service in detail in a non-promotional call once a practice had expressed interest following the brief introduction.

The ABMs and HDMs were all trained face-to-face according to the detailed information in the training slide (ref UK/RES-16082h) including a specific briefing document for the ABMs/HDMs (ref UK/RES-16082b) clearly stating some of the requirements such as below:

> 'You may introduce the service by giving a brief description of the service during the promotional call but may not instigate a detailed description about the service at the same time as a call when products are being promoted, this should be done in a non-promotional call.
>
> **You should ensure the following is adhered to:**
>
> - Napp support of this review must **NOT** be dependent on the customer prescribing a Napp product. This must be neither the fact in practice nor the impression given either verbally or in any documents connected with the project, internal or external
> - The prescribing of specific products must **NOT** be linked to the service either in conversation, or in writing, with any customer
> - Detailed discussion about the service must **NOT** be initiated at the same time as a call at which products are promoted.'

In addition, following the comprehensive training, the ABMs/HDMs had to score 100% in a validation test before any introduction of this service to practices (ref UK/RES-16082i).
Napp submitted that the complainant was specifically informed by his manager not to introduce the therapy review service and if he did so this was against instruction. The complainant's ABM when interviewed was critical about the complainant's understanding of the difference between a promotional and a non-promotional call and his selling skills (details were provided).

Napp submitted that neither the complainant nor anyone in his team introduced the asthma therapy review service. He was not therefore engaged in any form of validation training in call with a customer. He was not informed when these service nurses or pharmacists would be within his target surgeries because there never were any therapy review services within his entire region during the time he was employed. Theoretically as he had been trained on introducing the pharmacist-led asthma therapy review service then he could have access to the document. Yet again, if he did so this was against his manager's specific instructions and guidance. Napp would be interested to ask the complainant whether he did introduce a therapy review service to any of his target practices. Napp absolutely refuted the complainant's allegation that in pursuit of sales, compliance towards switches and Napp's briefing on switches from his manager was very lax during discussions within the field. Napp queried where the evidence for this was. Napp agreed that it was driving for business outcomes by the legitimate use of promoting switch, but did not confuse this with that of a *bona fide*, comprehensive asthma therapy review service. The complainant asserted that a health professional 'customer is encouraged to make changes through QOF and patient review in the first call and then to sign up the service in the second call'. Napp completely rejected this and challenged the complainant to provide any substantive evidence that this was the case.

In conclusion, Napp strongly disagreed with all of the complainant's allegations; it had provided comprehensive evidence that it had robust and compliant processes and training to implement a genuine non-promotional therapeutic review service via its third party supplier. In addition, a previous Napp case had been scrutinised by the Panel and no breaches of the Code were ruled in relation to Napp's ORCA service. Integral to this non-promotional service to the NHS, Napp had paid particular focus on Clause 19.2. Napp submitted that it had always maintained high standards as per Clause 9.1, and this activity had not brought discredit upon, or reduced confidence in the pharmaceutical industry as per Clause 2.

In response to a request for further information, Napp provided references from the leavepiece concerning medicines optimisation for a named CCG (ref UK/FLUT-15163) together with an explanation of each as follows:

- *MIMS Online [Accessed March 2016] Respiratory Asthma, COPD, Beta2 agonists, long-acting corticosteroids.* This referenced the three MIMS online resource to support the prices quoted in the leavepiece. Napp submitted that all prices were correct and no prices had changed since March 2016 for flutiform, Seretide Evohaler or Sirdupla.

- *GP Prescribing Data Extract, Health and Social Care Information Centre (HSCIC), 2015.* Napp submitted that this data provided the annual spend for many CCGs. Highlighted was the annual spend in the named CCG on the three strengths of Seretide Evohaler. The values were used as a starting point to derive patient numbers (see reference 8 below).

- *Patient Data, IMS Information Solutions UK Ltd, May 2015.* The data (under tab labelled 'calculation') took the annual spend on Seretide Evohaler in the named CCG (from reference 7 HSCIC data above, highlighted in pale orange) and what this translated into was actual patient numbers for each strength. The patient numbers were highlighted in yellow. Those numbers appeared in the table within the leavepiece. The potential cost savings were calculated by only taking those eligible Seretide Evohaler patients who would be within the licence for flutiform (because Seretide also had a paediatric licence). It then applied the flutiform and Sirdupla prices and subtracted that number from the cost of Seretide Evohaler to derive a cost saving, if there was a 100% switch of those patients within the flutiform and Sirdupla licences.

- *Methods for calculating flutiform appropriate patients from Seretide Evohaler Prescribing Data UK/FLUT-15142c.* Napp submitted that this reference provided detailed methodology for calculating the number of flutiform appropriate patients from Seretide Evohaler prescribing data. All caveats which were specified in reference 9 were included next to the table in the leavepiece. This clearly explained the methodology and the maths. The document included a worked example of calculations used for a different named CCG.

- *Methods for calculating Sirdupla appropriate patients from Seretide Evohaler Prescribing Data UK/FLUT-15142d.* Napp submitted that this reference substantiated the information in the leavepiece and provided the methodology for calculating number of Sirdupla appropriate patients from Seretide Evohaler. As above all mandatory caveats were included on the leavepiece.

PANEL RULING

The Panel noted that the parties' accounts differed; it was difficult in such circumstances to determine precisely what had happened. A judgement had to be made on the available evidence whilst noting that the complainant bore the burden of proof and had to establish his case on the balance of probabilities.

In relation to the complaint made to the PMCPA, the Panel was only able to consider matters within the scope of the Code. It considered the complaint as follows.

The Panel did not consider that the complainant alleged that Napp was advocating a 100% switch from Seretide Evohaler to Flutiform MDI; the complainant clearly stated that the fact that a 100% switch conversion could not be achieved was referenced in Napp's leavepiece.

The Panel noted that the complainant's concern was that the percentage switch conversion as set out in his KPIs by his ABM was unrealistic as there was no specific incentive schemes in place in any of the three named CCGs to switch exclusively to Flutiform MDI from Seretide Evohaler. The Panel noted that it appeared that the KPIs had been agreed by the complainant and his ABM and required the complainant to achieve a stated switch success rate within ten target GP practices within 6-8 months. It was stated that a switch should be 50% or more of a surgery's Seretide Evohaler marketshare to the equivalent dose of Flutiform. The Panel considered that the absence of incentive schemes in the CCGs did not necessarily mean that a switch would be unrealistic. Much would depend on whether health professionals considered that the benefits of a switch outweighed the work required to action it. The Panel did not consider that the complainant had proven that, on the balance of probabilities, the percentage switch was unrealistic for the reasons alleged. Nor that Napp in setting this KPI advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. No breach of Clause 15.9 was ruled.

The Panel further noted the complainant's concern that there was a stated rebate in place in the three named CCGs for GlaxoSmithKline's Seretide Evohaler and Sirdupla and therefore the cost saving figures in the leavepiece concerning medicines optimisation for one of the named CCGs (ref UK/FLUT-15163) were inaccurate and misleading. The Panel noted Napp's submission regarding the confidentiality of rebate percentages. The Panel further noted Napp's submission that the leavepiece compared NHS list prices and national prescribing data to ensure licensed age ranges were taken into account when calculating the potential cost savings. The Panel noted Napp's submission that the complainant had been briefed on the leavepiece and confirmed that he understood how to use it. The Panel considered that although it might be possible to buy medicines at less than the NHS list price due to the availability of discounts etc, it was not unreasonable for companies to base price comparisons on the NHS list price when this was made clear. The Panel did not consider that on the material before it the complainant had proven that, on the balance of probabilities, the leavepiece was misleading in that regard. On the narrow grounds alleged the Panel thus ruled no breach of Clauses 7.2, 7.4 and 9.1.

The Panel noted the complainant's allegation that he was under significant pressure from his ABM to convince practices to switch; the complainant was required to communicate his progress in each target practice on a weekly basis. The Panel reviewed two

emails provided by the complainant in support of this allegation and the allegation that discussing surgery prescribing data and patient switches in emails could potentially breach data protection laws. The first email was a follow-up email to the complainant from the ABM following the ABMs attendance at one of the complainant's GP practice meetings. The Panel noted Napp's submission that the email content displayed the ABM's concern that the likelihood of a switch in the named GP practice was low and this called into question the complainant's sales abilities. This email further highlighted the complainant's selling skills and suggested questions that he should be asking the GP. The second email predated the first and provided details of a business review held between the complainant and his ABM. The email highlighted the complainant's progress against his mutually agreed KPIs.

The Panel did not consider that it was necessarily unacceptable for ABMs to require weekly progress updates provided that it was done in a way that did not contravene the requirements of the Code. The Panel did not consider that the complainant had proven that the area business manager had applied sustained pressure on the complainant to deliver on business outcomes that did not comply with the Code as alleged. No breach of Clause 9.1 was ruled. Nor had the complainant proved that that the ABM requesting weekly updates would advocate directly or indirectly any course of action that would be likely to breach the Code. No breach of Clause 15.9 was ruled.

The Panel noted Napp's submission that the emails provided by the complainant did not contain any specific data about individual identifiable patients and the information sought was entirely anonymous in nature. The Panel further noted Napp's submission that to the extent that the emails mentioned individual health professionals, this information was a matter of public record and was being used by Napp for entirely legitimate business purposes and was subject to appropriate safeguards. The Panel was concerned about activities in relation to the Code. It was not for the Panel to determine whether Napp's activities were in line with data protection requirements *per se*.

Clause 1.11, however, stated that companies must comply with all applicable codes, laws and regulations to which they are subject. This clause had not been raised and the complainant had not provided evidence that the companies had been found in breach of data protection requirements. Given the circumstances the Panel therefore ruled no breach of Clause 9.1.

With regard to the use of the medicine for asthma overlap syndrome (AOS) and COPD as Flutiform MDI was not licensed for COPD, the Panel noted Seretide Evohaler's SPC and Napp's submission that Seretide Evohaler was not licensed to treat ACOS or COPD and therefore there was no need for such a consideration within its materials which referred to switching including the leavepieces (ref UK/FLUT-15163, UK/FLUT-16063a, and UK/FLUT-16007). Seretide Accuhaler was licensed to treat both asthma and COPD. The Panel did not consider that the material was misleading in that regard and no breach of Clause 7.2 was ruled.

The Panel noted that the complainant provided the incomplete front page of a document which stated 'A simple switch to Flutiform Real Difference' and an extract from another leavepiece which included a table highlighting differences between Seretide Evohaler and Flutiform. The Panel noted the complainant's allegation that describing the switch as simple was misleading as a simple switch should not be taken as like for like dose changes but should take into consideration the process of making changes which was more involved and required significant time investment from practices. The Panel noted that under the Code it would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch. The Panel noted that it would take time to review patients who potentially could be switched but considered that the reference to 'a simple switch' in the supplementary information to Clause 19.1 Switch and Therapy Review Programmes referred to switching from one medicine to another in relevant patients. The Panel noted that the complete document provided by Napp (ref UK/FLUT-16007) was titled 'A simple switch to Flutiform can make a real difference to your patients'. The leavepiece discussed some of the features of Flutiform followed by the results of a study in which patients were switched from Seretide Evohaler to Flutiform.

The Panel further noted Napp's submission that 'simple' was used to describe the switch from Seretide Evohaler to Flutiform as both products had very similar licensed indications for asthma maintenance therapy and any differences in licensed age ranges were clearly stated; both were pressurised aerosol MDIs; and both contained the same inhaled corticosteroid, so no steroid dose conversion was necessary.

The Panel noted that the leavepiece (ref UK/FLUT-16007) referred to the licensed indication of Flutiform including the age range for the various strengths and that it was for patients 12 years and older (low and medium strengths) and adults (all dosage strengths). The leavepiece stated that patients previously controlled on Seretide Evohaler 250mcg could be switched to Flutiform 250mcg and maintain good asthma control. A bullet point below in less prominent font stated that this was based on a 12-week pragmatic, open-label, randomised, controlled, non-inferiority trial in 225 adult patients with asthma. The leavepiece did not include the licensed indication for Seretide including the age range or the differences in licensed age ranges between Flutiform and Seretide as stated by Napp. The Panel queried why the leavepiece made no reference to the fact that patients aged 5 to 12 could not be switched from Seretide Evohaler to Flutiform. The second leavepiece referred to by the complainant (ref UK/FLUT-16063a) which was titled 'Do you have a medicines optimisation plan to switch asthma patients from Seretide Evohaler? Why choose Flutiform' included the claim 'A simple switch can make a real difference'. This leavepiece

asked the reader what was important to them when switching patients from Seretide Evohaler to Flutiform. The leavepiece compared Flutiform to Seretide Evohaler and Fostair in relation to a number of features including change in steroid from Seretide Evohaler, patient-facing dose indicator and refrigeration required prior to dispensing. Page 3 compared Flutiform and Fostair in terms of dose delivery and steroid percentage at the lowest daily dose. Whilst the leavepiece stated the licensed indication of Flutiform including the age range for the various strengths, it made no reference to the licensed indications of Seretide or Fostair including the age range. There would be patients who could simply be changed from Seretide to Flutiform. Notwithstanding its comments about the two leavepieces above, the Panel did not, however, consider that the complainant had proved that describing the switch in the leavepiece as simple was misleading due to the time investment required by surgeries in auditing patients appropriate for switching as alleged. Based on this very narrow allegation the Panel ruled no breach of Clause 7.2.

The Panel noted the complainant's statement that switches could be achieved either by influencing practices to make the switch in-house and/or introducing a nurse (ORCA) and/or pharmacist service, to practices if resource was required. The complainant alleged that although seen as an independent non-promotional service it was set up in such a way to switch inhaler medicines to Flutiform. The complainant stated that he was briefed about this service via Napp's intranet site but received no specific in-house, face-to-face training from Napp and no validation of a promotional call and non-promotional service call with customers. The complainant also stated that he was not informed when these service nurses and pharmacists would be present within his target surgeries. He could order non-promotional materials despite not having been trained by the training department and ABM. The complainant alleged that, in pursuit of sales, compliance towards switches and Napp's briefing on switches from the ABM was very lax during discussions in the field. As Napp was driving business outcomes for switches, the non-promotional service should not have been used as the introduction, was linked to Flutiform as a commitment from the customer to make changes through quality outcomes framework (QOF) and patient review in the first call and to then sign up the service in the second call.

The Panel noted Napp's submission that in a previous Napp case the OCRA service had been scrutinised by the Panel and no breaches of the Code were ruled in relation to the service. The Panel noted that it could only rule based on the evidence provided by both parties in relation to the allegations made. Each case was considered on its own merits. The Panel's ruling in Case AUTH/2808/12/15 in relation to the OCRA therapy review service stated that 'Whilst some concerns were outlined the Panel did not consider that the complainant in that case had proved his complaint on the balance of probabilities. The Panel did not consider that there was any evidence before it to demonstrate that the service as implemented was included in individual sales targets or was only offered where a switch was guaranteed as alleged. The Panel thus ruled no breach of Clauses 18.1 and 19.1. Subsequently no breach of Clauses 9.1 and 2 were also ruled'.

Turning back to Case AUTH 2956/5/17, the Panel noted there were differences since it considered the previous case. The current documents provided were dated between September and December 2016. There was no indication whether the materials had simply been changed to reflect the new pharmacist-led service or other changes had been made. The Panel had to consider the service in relation to the allegations about the promotional materials which focussed on switching patients to Flutiform. The Panel noted Napp's submission that account managers, including the complainant, were only allowed to introduce the service briefly and in accordance with the briefing document (ref UK/RES-16082c). Napp had further submitted that the complainant received a live 1 hour, on-line WebEx training on the new pharmacist-led review service and process. This was a 'virtual' face-to-face training which included a Q&A session and a follow-up briefing document to further clarify the process (ref UK/RES-16082c) which specified the dos and don'ts for account managers in terms of non-promotional vs promotional calls and to which was attached the service introduction document. Napp noted that the complainant acknowledged that he had read and understood the briefing document. The Q&A stated that once a therapeutic review was in progress in a practice, account managers were not allowed to discuss the asthma review service with any of the health professionals in that practice. The briefing included relevant requirements from the Code. The Panel noted Napp's submission that the complainant was not informed when these service nurses or pharmacists would be within his target surgeries because there were no therapy review services within his entire region during the time he was employed. The Panel further noted that the complainant was informed by his manager not to introduce the therapy review service and if he did so it was against instruction.

The Panel noted that a briefing document (ref UK/RES-16082c), the training slides for account managers and the material provided by the complainant set out what discussions could take place in a promotional call and a non-promotional call. The promotional call flow diagram covered two possible situations for customers which had agreed to switch, firstly where there was no request for assistance and secondly where assistance was requested. In both situations no therapeutic review would be offered. The flow diagram for the non-promotional call whereby the health professional had an interest in therapeutic review, the service introduction document was to be used and the practice referred to the ABM/HDM. The Panel did not consider the training materials were sufficiently clear given that the main promotional message for account managers was for a switch to take place. In addition, leavepieces promoting the switch (refs UK/FLUT-16007, UK/FLUT-16063a and UK/FLUT-15163) were to be left at the end of the call. There was no

flow diagram or other instructions in the training material for the situation when the service was briefly introduced during a promotional call. It was not clear from the briefing documents for account managers (ref UK/RES-16082c) or ABMs/HDMs (ref UK/RES/16082b) that if a practice had agreed to switch, the service could not be offered in that practice even in a subsequent non-promotional call by the account manager or an ABM/HDM. However, this did not necessarily mean that the therapy review service offered by Napp was linked to the promotion of Flutiform as alleged. The Panel noted its comments and rulings above and although concerned about the relationship between the promotional messages about switching and the service which provided resource to change patients' medication including to Napp's product Flutiform, it did not consider that the complainant had shown on the balance of probabilities that the arrangements failed to meet the requirements of Clause 19.2. The Panel therefore ruled no breach of Clause 19.2. The Panel did not consider that the complainant had provided evidence that in pursuit of sales, Napp's compliance and briefing on switches from the ABM were very lax as alleged. The Panel consequently ruled no breach of Clauses 9.1 and 2.

2 Call rates

COMPLAINT

The complainant pointed out that a Napp and contract agency communication which required for him to increase his call and contact rate did not reference Clause 15.4 of the Code relating to solicited/unsolicited and the frequency of calling and remaining Code compliant. The pressure to increase sales and call rate without referencing the Code was written freely in email communications both from Napp and the contract agency email. The complainant understood that the contract agency was not a member of the ABPI, however the instruction to increase his call rate was made by it as well and therefore there was an issue of responsibility from the agency to promote the Code on behalf of its client, Napp, which did not happen.

RESPONSE

Napp submitted that it did not require a call rate number from any of its account managers but did expect relevant and compliant customer contact to make sales in order to be a profitable business. All account managers were trained as part of Code compliance training and updates on the requirements of the Code with regards to frequency/the number of calls made on a doctor or other prescriber by a representative which should not exceed three on average per year. It was thus therefore highly surprising that the complainant felt surprised that he was put under pressure by his manager and contract agency to increase his contacts and calls with relevant health professionals. Napp stated that it was clear from the manager that the complainant was never asked to breach Clause 15.4; he was employed full time, working an average of 37.5 hours per week. Given that the complainant had seen only one target customer GP surgery per 5 weeks (=25 working days) when he was reviewed in 2016 Napp queried whether the complainant seriously proposed that that was acceptable.

Napp stated that this was further highlighted later in the email when discussing the sales activity which the complainant had recorded within the online customer relationship management (CRM) system. The email stated that 'In the period [in question] you appear to have seen around 20 GPs face-to-face, and just 4 practice nurse calls.' This was a period of 18 weeks and so was about 1 GP per week. A document provided by the complainant explained that he was asked to increase his call rates by the contract agency. There was no evidence in this email that the complainant was asked to breach Clause 15.4, either directly or indirectly.

Napp stated that it had interviewed the complainant's manager in detail and corresponded with the contract agency in order to establish his activity. The contract agency had stated that 'During legitimate performance management, [the complainant] was urged by [his] manager to increase [his] general activity, which was abnormally low. At no time did the agency ask or encourage [the complainant] to breach [the Code], either Clause 15.4 or any other provision. In particular, [he] was not asked or encouraged to increase frequency of calls on the same health professionals, nor to override such health professionals' wishes or cause inconvenience to them. [The agency] is well aware of the provisions of the [Code] and takes reasonable steps to ensure that they are not breached by its representatives'.

Napp followed up this response by asking what was meant by 'abnormally low' activity and was informed that this was with reference to the health professional calls recorded by the complainant in the CRM system. Napp also asked about what 'reasonable steps' were taken by the contract agency concerning the Code and received the following response:

> 'For experienced representatives, we ensure that we see a valid ABPI certificate prior to joining. In addition, we take and keep a copy of the ABPI certificate on file. We ensure employment references are requested and checked. We offer further support and training where required (for example if knowledge gaps are identified) working in conjunction with the client manager.'

Napp submitted that the complainant's ABM gave a very poor summary of the complainant's performance which led to the decision to terminate his contract early (details were provided).

Napp stated that, in conclusion, it was very clear that it had not breached Clause 15.9 (together with the supplementary information to Clause 15.4), it had maintained high standards at all times (not in breach of Clause 9.1) and that its employees had not undertaken any activities that would bring discredit upon the pharmaceutical industry and therefore was not in breach of Clause 2.

PANEL RULING

The Panel noted the email provided by the complainant as evidence that he was pressurised to increase his call and contact rate without reference to Clause 15.4 and remaining Code compliant. This email, sent by the third party agency discussed the complainant's progress in terms of improvement in his call rates and an increase in the number of 1:1 appointments confirmed. The Panel noted Napp's submission that the complainant was urged to increase his activity. The complainant had only seen someone from 4 out of his 30 accounts in five and a half months which equated to around one target GP surgery every 5 weeks. The Panel considered that whilst it might be prudent and good practice to refer to the requirements of Clause 15.4 whenever calls or contacts were discussed with representatives, given the complainant's call rates there was no evidence to show that Napp in encouraging the complainant to increase his activity had advocated either directly or indirectly any course of action which was likely to breach the Code. The Panel noted Napp's submission that all of its account managers received training with regard to the Code including the frequency/ number of calls made on a health professionals per year. The Panel ruled no breach of Clause 15.9. There was no evidence that Napp had failed to maintain high standards in this regard nor that the company had brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel ruled no breach of Clauses 9.1 and 2.

3 Speaker meetings

COMPLAINT

The complainant noted that Napp organised an external speaker through its Chest Sounds meetings as a tactic to access health professionals and follow-ups with the attendees after the meeting, however Napp did not provide any briefing about whether the speaker was only to be offered at nurse meetings and not GP meetings. The complainant provided documents where his ABM was reluctant to sponsor a meeting for a GP, writing in an email that a previous representative on the territory had 'suggested they were not of particular value'. The complainant was concerned that his ABM had been derogatory about a health professional and his GP group who were all prescribers, and was not offering a service based upon an interaction of a previous territory representative. The complainant alleged that Napp had shown unprofessional behaviour towards a health professional and his GP group. The complainant further stated that the contract agency suggested in its communication with him that such a meeting was linked to a return on investment. The complainant was not sure if Napp was copied into this communication. The contract agency briefing to the complainant was simple and in breach with no written reference to the Code to protect itself as an organisation.

RESPONSE

Napp noted the complainant's comments about speaker meetings and that his manager had been reluctant to support one meeting with a health professional because the GP was 'not of particular value'. Napp also noted the complainant's reference to the contract agency that meetings were linked to a return on investment. In that regard Napp stated that as part of its promotional activity within asthma it had found that, within the region covered by the complainant, asthma nurses in particular valued education on how to listen to and understand respiratory chest sounds. This had become a popular speaker meeting and was also a promotional meeting for Flutiform (examples provided). The speaker was a respiratory consultant physician. Napp submitted that from discussion with the complainant's manager it was clear that there was no need for a briefing on the target nurse audience; his manager had verbally agreed with the complainant that he would arrange such a meeting to interact with practice nurses interested in asthma. The complainant's manager had explained that what was missing from the complainant's letter was that despite several reminders he did not arrange the meeting, which he was supposed to do via a GP practice manager. The complainant's manager found this unprofessional and frustrating as dates and organisation with the consultant physician speaker were potentially damaging the relationship as the speaker would travel some distance to deliver the presentation. Finally, following several reminders from his manager, the complainant suggested an alternative 'quick fix' solution for the Chest Sounds meeting to be delivered to a well-known group of local GPs. This was referred to in an email from his manager to the contract agency. A particular sentence was highlighted within the email '([representative] who worked this territory previously suggested they were not of particular value)'. Napp noted that the complainant alleged that this was a derogatory comment about a GP and his GP group 'who were all prescribers.' In actual fact the feedback that the complainant's manager had had was that this group of GPs were known informally locally as the 'middle-aged doctor' group which had existed for some years and that around half were retired and hence this would be inappropriate, ie 'not of particular value'. Retired GPs could be perceived as members of the public if not in active NHS employment, and so it would be in breach of the Code to promote to them. This was why the complainant's manager was right to cancel the promotional meeting. The manager commented on this point that:

> 'In our last discussion around this ….., I specifically asked [the complainant] not to approach the GP lead for this group as I was keen to ensure we did this meeting for the right reasons, with the right customers, and not just for the sake of doing it. [The complainant] went ahead and approached [his] customer despite being asked not to.'

Napp submitted that this was clearly at odds with the complainant's allegations and it suggested that he was asked to elaborate further. The manager's comment was not derogatory and had been taken out of context. Napp denied a breach of Clause 9.1.

The Chest Sounds meeting would have been a promotional meeting and so did not come within the scope of Clause 19.2 of the Code. Napp therefore denied a breach of Clause 19.2, as well as of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the parties' accounts differed, it was extremely difficult in such cases to know exactly what had transpired. The complainant stated that Napp did not provide any briefing about whether the speaker was only to be offered at nurse meetings and not GP meetings. The Panel noted Napp's submission that it was verbally agreed by the complainant and his manager that the Chest Sounds meetings involving an external speaker would be arranged with practice nurses with an interest in asthma.

The Panel noted that Napp did not comment on the complainant's allegation that Napp had used the Chest Sounds promotional meetings as a tactic to gain access to health professionals and follow up with attendees after the meetings. The Panel considered that it was not necessarily unacceptable for meetings to be a means of interacting with health professionals. Noting its comments above and the complete absence of evidence, the Panel considered that the complainant had failed to show that there had been a breach of the Code with regard to the use of the Chest Sounds meetings. The Panel consequently ruled no breach of Clause 9.1 and 2. The Panel did not consider that Clause 19.2 was relevant as this applied to medical and educational goods and services and not to promotional meetings. No breach of Clause 19.2 was ruled.

The Panel noted that the complainant's ABM stated in an email to the third party agency that an account manager who worked the territory previously suggested they were not of particular value when referring to a group of GPs that the complainant suggested running a meeting with when the meeting with a group of nurses had not been confirmed. The ABM took the decision not to sponsor the meeting. The Panel noted Napp's submission that the feedback the ABM received from another account manager was that this group of GPs were known informally locally as the 'middle-aged doctor' group who had been around many years and half of whom were retired. Napp submitted that retired GPs were 'not of particular value' and could be perceived as members of the public and it would be in breach of the Code to promote to them which was why the meeting did not go ahead. The Panel did not consider that in referring to the group of GP's as being 'not of particular value' the ABM had been derogatory as alleged; it was not necessarily unacceptable for a pharmaceutical company to decide which health professionals to promote to based on a return of investment provided that requirements of the Code were met. The Panel did not consider that Napp had failed to maintain high standards and therefore ruled no breach of Clause 9.1.

Complaint received **8 May 2017**

Case completed **29 August 2017**