CASE AUTH/2722/7/14

ANONYMOUS EX-EMPLOYEE v ORION

Respiratory reviews

An anonymous, non-contactable, complainant who stated that he/she was an ex-employee of Orion Pharma UK was concerned about respiratory reviews being carried out in GP surgeries on Orion's behalf. Orion marketed three Easyhalers for the treatment of asthma (Easyhalers salbutamol, beclometasone and budesonide) and one Easyhaler for use in asthma or chronic obstructive pulmonary disease (COPD) (Easyhaler formoterol).

The complainant explained that Orion payed an external company to conduct the reviews to alter GPs' prescribing habits and although the reviews were independent, Orion knew that a cost based review would mean patients were switched to an Orion Easyhaler.

The complainant stated that at the start of the 2014 conference, representatives were told that signing up these reviews was critical for Orion's success that year and since then representatives had been under increasing pressure to sign up GPs. The complainant questioned how that could be if the reviews were non-promotional.

The detailed response from Orion is given below.

The Panel noted that the complainant was anonymous and non-contactable. As with all complaints the matter would be judged on the evidence provided by the parties; the complainant bore the burden of proof. The complainant in this case, who could not be contacted for further information, alleged that Orion had paid a third party to conduct respiratory review services which in effect served to switch patients to Orion medicines.

The Panel first examined how the representatives were briefed about the review service.

The Panel noted potential for confusion given that the same abbreviation was used to refer to the company conducting the reviews and a type of treatment. The Panel queried whether some representatives might assume that they were being encouraged to sign up GPs for the respiratory review service because it was the way to achieve the level of Easyhaler sales as set out on slides used at the January and May 2014 national sales meetings. The Panel further noted that a presentation given by a representative at the May conference referred to cost efficiencies and the Panel considered that the aim of this presentation was to discuss strategies which had been successful in getting GPs to sign up for the service.

It was clear to the Panel that Orion was promoting and the representatives were detailing, at least in part, Easyhalers as a less expensive prescribing choice that the prescriber could consider switching his/her patients to. A slide set entitled 'COPD and Asthma background', which appeared to be aimed at representatives, included a slide which referred to the aims and objectives of the respiratory review service and stated 'Clinical and Financial benefit without burdening practice Resources'. Notes accompanying the slide stated that if during a promotional visit a change in medication to an Orion product was agreed, the respiratory review service could not be offered as this would be a means of the company making sure that the change would be made. It was not stated what was to happen if a change to Orion's products was agreed in the separate non-promotional meeting that a representative might arrange to detail the service.

The Panel was extremely concerned about the impression that the leavepieces, which encouraged switching patients to Easyhaler and other material which detailed cost savings with Easyhaler, would give if they were also left with the leavepiece about the respiratory review service. The Panel noted Orion's submission that the respiratory review programme was initiated, at least in part, in response to the upward-spiralling spend on respiratory medicines. The Panel considered that given the content and tone of some of the promotional material, it was not unreasonable to think that some GPs might be persuaded to use the service to switch patients from their current inhalers to the generally less expensive Easyhalers. In this regard, the Panel noted that although practices could agree their own bespoke review and thus identify the patient cohorts they wanted to be included, the second patient cohort referred to in the template review protocol provided was 'Patients receiving non practice preferred inhaled preparations to be clinically assessed to highlight opportunities for improved management & change to practice preferred device/preparation to improve budgetary efficiency'. The Panel queried whether this cohort of patients would be clinically reviewed as it appeared that they might, for no clinical reason, be switched to alternative therapies that were either 'practice preferred' or which improved budgetary efficiency. The Panel noted Orion's submission that representatives delivered this document to surgeries in a non-promotional call to show what the service consisted of and explain the nature of the service before the practice signed up to the service. The Panel further noted that the letter template for patients in cohort 2 appeared to show that such patients could have their inhalers changed without a face-to-face consultation with a health professional; the patient was advised that if they would like to discuss the changes that had been made, which could include a new device and/or dosage regimen, then they could see the practice nurse or direct any queries to their community pharmacist who would be able to demonstrate the new device. The Panel queried whether the arrangements for patients

in cohort 2 were acceptable given how important compliance and the correct use of devices was to the control of asthma.

The Panel noted Orion's campaign promoted a switch to Easyhaler devices on the basis of cost. There must be a clear, visible demarcation between any promotional activity and the offer and implementation of the therapeutic review otherwise the review could be seen as a switching service contrary to the Code. The Panel noted its comments above about the representatives' briefing. In the Panel's view, some representatives would have been left with the unacceptable impression that the service was to be used as a vehicle to increase sales. The Panel also noted the unacceptable impression given by the Easyhaler leavepieces when left at a practice with the service leavepiece and the second patient cohort referred to in the protocol. In the Panel's view, and on the balance of probabilities, the combined effect of the above was that prescribers were more likely to switch patients to Easyhaler devices; the Panel ruled breaches of the Code. The Panel considered that to provide representatives with materials which referred to switching and then ask them to leave material which introduced a therapy review programme meant that high standards had not be maintained. A further breach was ruled. The Panel noted that the complainant had made no specific allegation with regard to the conduct of any representative. In the Panel's view, by using the materials provided and introducing prescribers to the service, representatives had complied with their briefings and in that regard had not failed to maintain high standards. The Panel ruled no breach of the Code.

The Panel acknowledged the clinical value of a therapy review service for asthma patients and although it had particular concerns about cohort 2 (if the GP decided to include such a cohort in the review), it considered that on balance the respiratory review service had not been such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

An anonymous, non-contactable, complainant who stated that he/she was an ex-employee of Orion Pharma UK Ltd was concerned about respiratory reviews being carried out in GP surgeries on Orion's behalf. Orion marketed three Easyhalers for the treatment of asthma (Easyhalers salbutamol, beclometasone and budesonide) and one Easyhaler for use in asthma or chronic obstructive pulmonary disease (COPD) (Easyhaler formoterol).

COMPLAINT

The complainant explained that Orion payed an external company to conduct respiratory reviews in GP surgeries to alter their prescribing habits. The complainant stated that although the reviews were independent, Orion knew that a cost based review would mean patients were switched to an Orion Easyhaler.

The complainant stated that at the start of the 2014 conference, representatives were told that signing up these reviews was critical for Orion's success that year and since then representatives had been under increasing pressure to sign up GPs to undergo review. The complainant questioned how that could be if the reviews were non-promotional.

The complainant stated that he/she had been told that at a recent conference, a representative [from a named territory] gave a presentation which compared how many reviews he/she had arranged and the rise in sales; representatives in attendance were told to speak to the presenter to find out how he/she had done it.

When writing to Orion, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 18.1 and 18.4 of the Code.

RESPONSE

Orion submitted that it was a relatively small team that prided itself on its open approach to communication. Its two regional sales managers managed eighteen respiratory representatives; a further five representatives worked in other therapeutic areas. Orion provided details of its respiratory range of products: Easyhaler Salbutamol Sulphate, Easyhaler Beclometasone, Easyhaler Budesonide, Easyhaler Formoterol.

Orion liked to think that team members could bring their concerns to the management's attention informally, but it also had a clear public interest disclosure or 'whistle-blowing' policy in the UK and so it was very disappointed that its former employee felt unable to raise his/her serious concerns through one of these mechanisms whilst still employed. Orion submitted that it took such matters extremely seriously and as a consequence, launched an internal review and investigation. Senior members of the medical department interviewed key individuals involved in providing the respiratory review service and reviewed all current documents and associated working practices.

The respiratory review service

Orion funded an independent third party service provider to conduct respiratory reviews as a service to medicine; such reviews were conducted to improve the management of asthma and COPD to the benefit of patients and the NHS, and not to alter GPs' prescribing habits as alleged. The programme of reviews was initiated in 2009 to improve the quality of asthma treatment across local health economies. To date over two hundred reviews had been carried out at practices. The programme was initiated in response to the upward-spiralling spend on respiratory medicines and high levels of hospital admissions for respiratory problems. Orion submitted that enabling asthma to be more efficiently managed in primary care, benefitted patients and the NHS.

Orion submitted that the respiratory reviews were essentially clinical audits. They were conducted with all reasonable skill and care and complied with relevant established current professional standards and the code of ethics set down by the General

Pharmaceutical Council (GPhC). The aims and objectives of the audits were to:

- Facilitate active case finding of patients with undiagnosed COPD in order to improve early identification and management and thus disease outcomes and the patient's quality of life.

- Identify patients at risk of asthma or COPD exacerbations. Risk stratification of patients allowed the practice to prioritise work streams within COPD and asthma management. Improved management of high risk patients supported a reduction in respiratory referrals and overall disease morbidity and mortality.

- Identify and realise prescribing efficiencies to minimise the budgetary impact of earlier pharmacological interventions in high exacerbation risk and the pharmacological management of newly diagnosed patient groups.

Orion stated that the service provider operated entirely independently of Orion in accordance with the clinical requirements of the practice and the needs of each patient. Orion was not able to influence the use of any specific medicine or product during this process. Use of the respiratory review service was not connected with the prescription of any Orion product. The protocol used directed the cycle of the clinical audit and the therapy review reflected many of the principles laid out in the best practice guidance for clinical audit by the NHS using risk stratification tools to profile patients whilst tackling medicines management objectives relating to therapy. Each practice that used the service agreed its own bespoke review specification and objectives with the service provider pharmacist. Clinical assessment of patients was in accordance with the British Thoracic Society (BTS) Guidelines, local formularies and practice review specification; patients' medical records were reviewed individually. The protocol included options for: case finding for COPD patients; identification of sub-optimally controlled asthma patients; 'stepping down' of treatment for well controlled asthma patients; rationalisation of prescribed inhaler preparations and identification of any other patient cohorts that the practice chose. The service provider pharmacist prepared recommendations within this framework for the doctor responsible for prescribing decisions. All prescribing decisions remained solely with the physician.

Orion noted that the complainant alleged that the company knew that a cost based review would mean that patients would be switched to an Easyhaler. Orion submitted that as was clear from the protocol, the review service was based on optimising patient treatment and there was no specific option for a 'cost based review'. Any changes to treatment were made on the basis of reviewing the patients' medical records and the prescriber decided which treatment to use.

In line with the requirements of the Code, representatives were instructed that the provision of the service was non-promotional and so it must not be discussed during a promotional appointment. Representatives were advised that in order to comply with this requirement they must not carry out promotional and non-promotional activities at the same visit, and that the service could not be provided to a practice that had stated its intention to change patients to Orion products as this would, effectively, mean Orion had paid for prescriptions. Representatives could introduce the service by means of a brief description and/or delivering materials but could not instigate a detailed discussion about the service in the same call in which they promoted products.

Orion submitted that when representatives joined the company their initial training included training on the respiratory review service by one of the marketing team. A copy of the presentation was provided. Regional sales managers continually reviewed representatives' training needs during field visits and provided coaching or arranged additional training as necessary.

Briefings at the January 2014 and May 2014 sales conferences

Orion submitted that it was careful to ensure that any discussion of the respiratory review service at sales meetings (held in January, May and September each year) was in a separate section of the agenda and not directly linked to any sales presentations. For example, discussions would be separated by tea breaks and lunch from the sales sections.

Orion noted that the complainant alleged that at the start of the 2014 conference the representatives were told that signing up of these reviews was critical for the success of Orion that year. Orion acknowledged that the respiratory review service was discussed at the January 2014 sales conference but it was never described as being critical for Orion's success.

The session about the respiratory review service was a minor section of the presentation which took the form of a reminder that a new service leavepiece was available. The sales team was advised that the leavepiece could be left with customers at the end of a promotional meeting but that details of the service could not be discussed with customers at that time. Less than 15 minutes was spent on this item during a two day meeting. Copies of the presentation from the January sales meeting, the leavepiece and associated briefing material were provided.

Orion submitted that the findings of its internal enquiry based on interviews with representatives and managers showed that at the January sales meeting the Easyhaler brand was described as important, vital and critical to the company; however, none of these words were used to describe the use or importance of the respiratory review service to Orion. Those interviewed described the value of the service to Orion as 'not vital to Orion but important' and more generally in terms of value to the customer, for example 'offering value to the customer and a helpful service'.

Orion noted that the complainant stated that 'Since that conference representatives have been under increasing pressure to sign up GPs for reviews'.

Orion submitted that the company had never asked representatives to increase the number of general practice 'sign-ups' for this service. Representatives were not measured or targeted on respiratory reviews and were not bonused on activity in relation to them.

Orion noted that the complainant went on to state 'I was told that at the recent conference a representative from [a named territory] gave a presentation on the comparisons of how many reviews he/she had signed up and the rise in sales. Representatives at the presentation were told to speak with the presenter to find out how he/she did it.' Orion submitted that this did not take place.

Orion submitted that at the most recent sales meeting (May 2014), there were four ninety minute workshop sessions on respiratory topics. Topics discussed were 'Implementing local guidelines/ formularies', 'Selling the Easyhaler Steroids - Use of materials', the 'My Well-being' application for smartphones and a session on the introduction of the respiratory review service to customers. Each session began with a short informal introduction by a member of the sales team followed by unscripted round table discussions amongst the representatives. One of these workshops was introduced by the representative responsible for the territory referred to in the complaint and took place during the 'Introduction of the respiratory review service to customers' session. This session was separate from the sales content of the meeting and the representative prepared some slides to act as an aide memoire and these were shown to the group. The session explained how a local clinical commissioning group (CCG) used the respiratory review service to implement its respiratory guidelines (a copy of the presentation was provided). In contradiction to the complainant's assertion, the presentation did not show the number of reviews that had taken place, nor did it provide any sales data.

The representative was interviewed as part of the investigation and confirmed that the aim of the session was to describe the benefit of working in partnerships with the CCG during the implementation of its local guidelines and that 'sales' were not mentioned during the session and the sales team was not instructed to talk to the presenter to find out more information on increasing sales using this mechanism. All questions and discussions during the workshop were on the subject of working with CCGs to implement guidelines.

Actions

Orion stated that in response to this complaint, its internal review and investigation had resulted in a number of immediate actions:

- The nature and significance of the complaint has been communicated to all staff including the sales team, and representatives had been reminded of correct procedures associated with the use of the respiratory review service, the importance of complying with the Code and the procedures for raising concerns.
- The medical team would conduct a further, detailed review of all processes and materials connected to the respiratory review service and report its findings together with an action plan for any remedial activities that might be required.

Orion submitted that as a result of its investigations it was disappointed to report that the presentations at the May sales meeting were not certified before use; the failure to comply with company procedures was due to a prolonged period of serious illness during the preparation period for the sales meeting and a lack of appropriate delegation of tasks. The respiratory review training presentation had not been certified. This appeared to have been due to a lack of understanding of requirements. A programme to retrain and validate the sales managers and marketing team on company procedures for the review and approval of materials had been initiated.

Conclusions

Orion submitted that in its view, the complainant's concerns could and should have been dealt with by using the company complaints, whistle-blowing or grievance procedure. From its investigations Orion was confident that the respiratory review service was not used as a promotional tool or linked in any way to the promotion or prescription of Orion medicines, and that the independent service was of value to the NHS. It was not supplied or offered in connection with promotion or as an inducement to prescribe and was therefore not in breach of Clause 18.1. The service provided a genuine therapeutic review, which aimed to optimise patient treatment through consideration of a range of relevant treatment choices and was consistent with the requirements of Clause 18.4.

Consequently Orion did not believe that either the respiratory review service itself, or the way it was offered to customers were such as to bring discredit upon or reduce confidence in the industry and that a breach of Clause 2 could be ruled. However, the use of uncertified internal training materials identified during the investigation of this matter meant that Orion had failed to maintain high standards and on that basis it acknowledged a breach of Clause 9.1.

Orion submitted that its representatives offered the respiratory review service to customers as a non-promotional activity and it had no influence over any outcomes of the review. Orion submitted that its enquiry had failed to elicit any information that suggested its representatives had not maintained a high standard of ethical conduct or complied with all relevant requirements of the Code and there had been no breach of Clause 15.2.

In response to a request for more information, Orion provided copies of all current materials associated with the respiratory review service. Orion stated that as the service provider worked independently of Orion, Orion did not provide any briefing documents to the service provider pharmacists.

The audience for each item was as follows:

Item	Audience
Respiratory Review Protocol	GPs, CCG stakeholders, practice nurses, respiratory nurses, respiratory physicians
Letter Template for cohort 1 – COPD patients with FEV1 >50% without long acting beta agonist (LABA) or long acting muscarinic antagonist (LAMA) therapy	Patients
Letter template for cohort 2 – Patients receiving inhaled preparations outside of the practice preference -including LABA and LAMA	Patients
Cohort 3 – Patients at BTS step 3 (lowest dose) to be considered for step down to having a separate short-acting beta agonist (SABA) and inhaled corticosteroid	Patients
Briefing document for respiratory prescribing review leavepiece	Representatives
Adherence to prescribed medication letter	Patients
Change of therapy letter	Patients
Change of preparation letter	Patients
Invite to routine asthma/COPD review	Patients
Respiratory prescribing review introductory leavepiece	GPs

Copies of all current Easyhaler promotional material were provided.

Orion submitted that the representatives delivered the template Respiratory Review Protocol (reference EAS4044(1)) to surgeries in a non-promotional call to show the GP/practice what the service consisted of and explain the nature of the service and what the service provider pharmacist would do, before the practice signed up to the service. The service provider pharmacist was responsible for completion of the protocol in conjunction with the GP/practice during the respiratory review.

In response to a further request for more information, Orion reiterated that the Respiratory Review Protocol (EAS4044(1)) was the document that the service provider pharmacist completed with the lead GP and practice manager. All work undertaken by the service provider pharmacist during the review was entirely driven by and within the scope of this pivotal certified document only after the document had been signed by the lead GP and practice manager. The work of the service provider pharmacist was therefore controlled and directed by the protocol document, adherence to which was monitored by the practice signatories, service provider regional managers and regional trainers. The service provider managers and trainers were senior pharmacists who undertook regular field visits with the service provider pharmacist to assess and support them in all aspects of their work.

Orion stated that each service provider pharmacist had an average of seven years' post-graduate clinical experience. Each pharmacist underwent a six-month training period, during which they received a minimum of thirty training days via a mix of classroom, on the job training/shadowing of colleagues, and in-service training from the service provider regional managers and regional trainers. Only on successful completion of this training programme were the service provider pharmacists signed out of their probationary period, beyond which they continued to be regularly field visited by regional manager and regional trainers. A copy of the service provider internal field visit proforma, which was completed as a training record during these visits was provided. All training was documented in line with GPhC guidance. The clinical skills of the service provider pharmacist combined with training and in-service support given by the service provider gave each pharmacist the technical skills to deliver the respiratory review service. The Respiratory Review Protocol (EAS4044(1)), signed by the lead GP and practice manager, gave the service provider pharmacist the specific scope, direction and permissions required to deliver the review.

Orion explained that as part of the six-month induction programme, the service provider trained its pharmacists on the Code. The company was assured that the service provider pharmacists were aware of the requirements of the Code in relation to the wide range of services that the service provider delivered on behalf of a wide range of clients. The latest version of the Code was available to all service provider pharmacists at all times, with any significant changes briefed out at internal meetings. The service provider regional managers and regional trainers regularly assessed their teams of pharmacists for awareness of and compliance with the Code when delivering services that involved Orion. This was monitored during routine field visits and all training was documented.

Orion provided a copy of the agreement between it and the service provider which it noted stated payment and procedural terms and conditions, and the details of service delivery referred to the pivotal Respiratory Review Protocol document (EAS4044(1)).

With regard to a further request for more information, Orion provided a copy of the Pharmacist Briefing Document that applied to the service provider pharmacists. This was a service provider document used by that organisation to brief its staff.

Orion confirmed that a written signature of permission was captured for each and every patient in order to permit the service provider pharmacist to implement a treatment change.

The service provider pharmacist presented information to the GP on a data capture sheet which included a free text section. This included the result of a comprehensive clinical assessment and collation of data in order to ensure an informed treatment decision (as per the protocol).

The briefing document confirmed that service provider pharmacists must get the GP's signature consenting to any changes he/she wished the service provider pharmacist to make. Page 10 of the protocol indicated that changes were agreed on an individual basis via written authorisation. This authorization was the GP's signature; with a tick added once any change was implemented.

Section 3-6 of the protocol allowed the service provider pharmacist to take direction in order to follow the prescriber's specification regarding preferred treatment pathways. This direction was used to support the rationale for treatment change but did not preclude, but rather supported the individual decision taken for each patient by the patient's GP. All changes of treatment were documented in each patient's notes.

With regard to the service contract, the service provider issued a general service contract that was used when providing services to a range of commissioning organisations such as the NHS, research organisations and the pharmaceutical industry. Not all of the stipulations within the contract were relevant to Orion, for example the 'initial shadowing and supervision of [service provider] staff' would not be appropriate in the service at issue, but would be appropriate to an NHS organisation. Therefore, as stated above, because the service provider worked independently of Orion, Orion did not provide any briefing documents to the service provider pharmacists.

Orion stated that the service contract was dated May 2014 because this was when the agreement was last updated. This agreement superseded an earlier contract dated February 2011.

In response to a final request for more information, Orion stated that two sets of slides used at the sales meeting used the same abbreviation to refer to two different things. The phrase used by the representative, 'Utilise Techs effectively', referred to collaboration with pharmacy technicians in the local medicines management team. The representative liaised with the pharmacy technicians to ensure that GP practices were aware of local services that were provided by the medicines management team; which in turn would help facilitate GP practices 'signing-up' for such services. No notes were prepared by the representative for this presentation.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. As with all complaints the matter would be judged on the evidence provided by the parties; the complainant bore the burden of proof. The complainant in this case, who could not be contacted for further information, had alleged that Orion had paid a third party, to conduct respiratory review services which in effect served to switch patients to Orion medicines. The complainant further alleged that representatives were under increasing pressure to get GPs to sign up for the service.

The Panel first examined how the representatives were briefed about the respiratory review service and noted that in some materials an abbreviation referred to the name of the service provider whilst in others the same abbreviation referred to a type of treatment. This was not helpful. The Panel noted that at the national sales meetings held in January and May 2014, a slide headed 'Easyhaler Strategy' had been used at least twice at each meeting. The slide stated 'Achieve £6M in sales by growing [abbreviation] and maintaining Formoterol sales growth'. Orion explained that in this presentation the abbreviation stood for a type of treatment but the Panel queried whether some representatives might assume it related to the service provider and that they were being encouraged to sign up GPs for the respiratory review service because it was the way to achieve the £6M Easyhaler sales. The Panel further noted that a presentation given by a representative at the May conference referred to cost efficiencies and the first two bullet points on slide 3 stated 'Deliver cost savings in line with protocol' and 'Utilise [abbreviation] – CCG, Public Health, Networks' respectively. Orion explained that in this presentation the abbreviation related to the service provider. The second bullet point on slide 3 was also used as the first bullet point on slide 4. Slide 5 referred to the use of technicians to 'endorse sign up'. The Panel considered that the aim of this presentation was to discuss strategies which had been successful in getting GPs to sign up for the service.

The Panel noted that representatives were provided with leavepieces for the Easyhaler and for the respiratory review service. A one page, A4, Easyhaler leavepiece (ref EAS4354, prepared May 2014) was headed 'Real Life Research in Asthma' and detailed a study by Price *et al* (2014); it was sub-headed, 'Switching real-life asthma patients from other types of inhaler to the Easyhaler for the administration of inhaled corticosteroids (ICS); an historical, matched cohort study'. In the Panel's view the leavepiece encouraged recipients to consider switching their patients currently on other inhaled corticosteroids to an Easyhaler corticosteroid device. The prescribing information for Easyhaler beclometasone was on the reverse. Price *et al* was

also used as the basis for an advertisement in a conference brochure (ref EAS4349, prepared July 2014) with similar text to that in the leavepiece just described. A cost comparison guidance sheet (ref EAS4036B(5), prepared May 2014) detailed the cost savings that could be made by prescribing Easyhaler devices rather than other inhalers and another leavepiece (ref EAS4042b(1)) was sub-headed 'Easyhaler Formoterol – has the lowest 28 days treatment cost of all inhaled LABAs or LAMAs'. The representatives were also provided with a Cost Comparison Excel Tool (ref EAS3502e(3)); the accompanying covering letter stated 'Using the selection of inhalers that you made and changing them to Easyhaler, the estimated annual saving would be as follows:'. In the Panel's view it was clear that Orion was promoting and the representatives were detailing, at least in part, Easyhalers as a less expensive prescribing choice that the prescriber could consider switching his/her patients to. In that regard, it noted that in a slide set entitled 'COPD and Asthma background', which appeared to be aimed at representatives, slide 6 referred to the aims and objectives of the respiratory review service and stated 'Clinical and Financial benefit without burdening practice Resources'. Notes accompanying the slide stated that if during a promotional visit a change in medication to an Orion product was agreed, the respiratory review service could not be offered as this would be a means of the company making sure that the change would be made. It was not stated what was to happen if a change to Orion's products was agreed in the separate non-promotional meeting that a representative might arrange to detail the service.

With regard to switching the Panel noted that the supplementary information to Clause 18.4 of the Code, Switch and Therapy Review Programmes, stated that 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 even if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements would be seen as companies in effect paying for prescriptions which was unacceptable. In that regard the Panel was extremely concerned about the impression that the leavepieces described above would give if they were also left with the leavepiece about the respiratory review service (ref RESP4270, prepared December 2013) which stated that one of the outcomes of the service would be to 'Achieve best value from treatment' and that the practice report could include 'Identification of prescribing efficiencies in order to minimise the budgetary impact of earlier and/or more appropriate treatment interventions across the wider respiratory patient group'. The Panel noted that in the briefing document for the leavepiece, representatives were instructed that a detailed discussion of the respiratory review service should be conducted in a separate appointment following on from, and completely separate to, Easyhaler promotional activity. The Panel noted Orion's submission that the respiratory review programme was initiated, at least in part, in response to the upward-spiralling spend on respiratory medicines.

The Panel considered that given the content and tone of some of the promotional material, it was not unreasonable to think that some GPs might be persuaded to use the service to switch patients from their current inhalers to the generally less expensive Easyhalers. In this regard, the Panel noted that although practices could agree their own bespoke review and thus identify the patient cohorts they wanted to be included, the second patient cohort referred to in the template review protocol provided (ref EAS4044(1)) was 'Patients receiving non practice preferred inhaled preparations to be clinically assessed to highlight opportunities for improved management & change to practice preferred device/preparation to improve budgetary efficiency'. The Panel queried whether this cohort of patients would be clinically reviewed as it appeared that they might, for no clinical reason, be switched to alternative therapies that were either 'practice preferred' or which improved budgetary efficiency. The Panel noted Orion's submission that representatives delivered this document to surgeries in a non-promotional call to show the GP/practice what the service consisted of and explain the nature of the service and what the service provider pharmacist would do, before the practice signed up to the service. The Panel further noted that the letter template for patients in cohort 2 appeared to show that such patients could have their inhalers changed without a face-to-face consultation with a health professional; the patient was advised that if they would like to discuss the changes that had been made, which could include a new device and/or dosage regimen, then they could make an appointment to see the practice nurse. Patients were also advised that they could direct any queries they had to their community pharmacist who would also be able to demonstrate the new device. The Panel queried whether the arrangements for patients in cohort 2 were acceptable given how important compliance and the correct use of devices was to the control of asthma.

The Panel noted Orion's campaign promoted a switch to Easyhaler devices on the basis of cost. In the Panel's view, the company must be especially vigilant to ensure that any therapeutic review offered in the same therapeutic field complied with Clause 18.4 and its supplementary information. There must be a clear, visible demarcation between any promotional activity and the offer and implementation of the therapeutic review. Were it otherwise, the review would be seen as a switching service contrary to Clause 18.4. The Panel noted its comments above about the representatives' briefing. In the Panel's view, some representatives would have been left with the unacceptable impression that the review was to be used as a vehicle to increase sales which was contrary to the Code. The Panel also noted the unacceptable impression given by the promotional leavepieces when left at a practice with the service leavepiece and the second patient cohort referred to in the protocol. In the Panel's view and on the balance of probabilities the combined effect of the above factors was that prescribers were more likely to switch patients to Easyhaler devices; the Panel ruled a breach of Clause 18.4 and thus of

Clause 18.1. The Panel considered that to provide representatives with materials which referred to switching and then ask them to leave material which introduced a therapy review programme meant that high standards had not be maintained. A breach of Clause 9.1 was ruled. The Panel noted that the complainant had made no specific allegation with regard to the conduct of any representative. In the Panel's view, by using the materials provided and introducing prescribers to the service, representatives had complied with their briefings and in that regard had not failed to maintain high standards. The Panel ruled no breach of Clause 15.2.

The Panel acknowledged the clinical value of a therapy review service for asthma patients and although it had particular concerns about cohort 2 (if the GP decided to include such a cohort in the review), it considered that on balance the respiratory review service had not been such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

During its consideration of this case the Panel had a number of concerns about the materials provided and the conduct of the respiratory review service. With regard to the materials, the Panel noted Orion's submission that the presentations at the May sales meeting and the respiratory review training presentation were not certified before use. Given that this matter was not the subject of the complaint, the Panel could not make any ruling upon it. The Panel also noted that the agreement between the service provider and Orion was a general service contract that the service provider used when it provided services to a range of commissioning organisations such as the NHS, research organisations and the pharmaceutical industry. Not all of the clauses within the contract were relevant to Orion. In the Panel's view this was unacceptable; if some of the clauses were not applicable they should at least have been scored out of the signed contract. It was impossible to know the exact details of what had been agreed between the parties.

The Panel was concerned that Orion appeared to take very little responsibility for the service provider pharmacists acting on its behalf. The Panel requested that Orion's attention be drawn to supplementary information in the Code which stated, *inter alia*, that service providers must operate to detailed written instructions provided by the company. Orion had stated that it did not provide any briefing documents to the service provider pharmacists. Although the company submitted that the pharmacists had an average of 7 years' post-graduate clinical experience, the Panel noted that in the briefing document given to them by the service provider it was stated 'Familiarise yourself with the dynamics of the BTS guidelines for asthma and NICE guidelines on COPD'. The same document provided a brief resumé of useful clinical information on various therapy options. In that regard the pharmacists did not appear to be respiratory specialists.

Complaint received **14 July 2014**

Case completed **27 October 2014**