COMMUNITY PHARMACIST v GLAXOSMITHKLINE

Resource booklet for Pharmacists

An anonymous, non contactable complainant who stated he/she was a community pharmacist submitted a complaint about a National Pharmacy Association (NPA) booklet 'Managing COPD [chronic obstructive pulmonary disease] in the community, Resources for pharmacists', which had the GlaxoSmithKline and NPA logo printed on the front page. The booklet was written and developed by the NPA and GlaxoSmithKline had provided funding and checked it for scientific accuracy in respect to any GlaxoSmithKline products. The booklet mentioned the Evohaler and Accuhaler devices which were GlaxoSmithKline devices for various GlaxoSmithKline medicines.

The complainant referred to a table on page 28 under a heading 'COPD inhaler devices' which referred to the Evohaler Device as an example of a standard MDI. The complainant was concerned that the reference to the 'Evohaler' device could refer not only to the Ventolin Evohaler, which was licensed for COPD, but also to the Seretide Evohaler which was not so licensed. The 'Evohaler' trade name could therefore cause confusion and acceptance that Seretide Evohaler was licensed for COPD which it was not. This was something that should be highlighted during a medicine use reviews (MUR) and (NMS) intervention which was not referenced in any of the MUR and new medicines services NMS documentation within the booklet.

The complainant questioned the bias towards some inhaler devices that had been listed and others which had higher prescribing within his/her locality and not been referenced.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's role in relation to supporting the booklet was limited to funding and checking it for factual accuracy with respect to its own products; its content was otherwise a matter for the NPA. However GlaxoSmithKline submitted it would make the booklet available for a promotional purpose which meant that it was subject to the Code. The Panel noted GlaxoSmithKline's submission that it had not proactively distributed the booklets.

The Panel noted GlaxoSmithKline's submission that Evohaler products; Ventolin Evohaler and Seretide Evohaler, were not licensed for COPD whereas Serevent Evohaler was. The Panel noted the complainant's statement that Ventolin Evohaler was so licensed. In this regard the summary of product characteristics (SPC) for the Ventolin Evohaler stated at section 4.1, that Ventolin provided short-acting (4-6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction. The SPC then stated that it was 'particularly suitable for the relief and prevention of asthma symptoms' and that it was 'particularly valuable as relief medication in mild, moderate or severe asthma'. There was no mention of COPD in the indication section of the SPC.

The Panel noted that pages 26-38 were headed 'COPD inhaler devices', the table in question started on page 28 and was headed 'The different types of inhaler devices available and instructions for their use*'. This table listed 7 types of device providing information about the device type, examples of devices and instructions for their use. The heading to the table bore an asterisk which related to a footnote to the table which appeared as five bullet points on page 34. One bullet point stated, *inter alia*, that the licensed indications varied, and that some might only be licensed for use in asthma and not COPD – individual products' SPCs should be referred to for more information. The Panel noted that GlaxoSmithKline had requested this footnote be inserted as a correction to the draft booklet.

The Panel did not consider that it was necessarily misleading to refer simply to 'Evohaler' in Table 8 as an example of a standard MDI device. The Panel noted that this was clearly an area of potential difficulty as demonstrated by the complainant's confusion.

The booklet included a number of loose insert 'crib sheets' for MUR or an NMS. Neither specifically mentioned the need to check that medicines were licensed for COPD, nor did the crib sheet for a NMS. However, the Panel considered that this in itself was not necessarily inappropriate given that a MUR would look at all medicines prescribed. If concerned after a MUR or NMS consultation, pharmacists could query which medicines had been prescribed and why and take further action as appropriate.

The Panel did not consider that the references to Evohaler in the booklet meant that GlaxoSmithKline had promoted Seretide Evohaler for an unlicensed indication as alleged. On balance the Panel did not consider that the reference to Evohaler as an example of a device for use in COPD was misleading as alleged. The Panel considered that it would have been helpful if the relevant footnote had appeared at the outset rather than 6 pages later where it might be read as the heading to table 9 rather than the footnote to table 8. However, the intended audience would know that not all medicines licensed for asthma were licensed for COPD. No breaches of the Code were ruled.

With regard to the lack of mention of other devices the Panel noted GlaxoSmithKline's submission that three more recent DPIs were not used as examples. The foreword which included 'Details of available COPD inhaler devices and other equipment' and

the heading to pages 26-38 'COPD inhaler devices' could be seen as implying all devices would be listed. However, table 8 was clear that 'Examples of devices' were listed. The Panel considered, that, on balance, table 8 was not an unfair comparison or misleading as alleged and ruled no breach of the Code.

The Panel noted its rulings above and considered that GlaxoSmithKline had not failed to maintain high standards and no breach of the Code was ruled.

An anonymous, non contactable complainant who stated he/she was a community pharmacist submitted a complaint about a National Pharmacy Association (NPA) booklet 'Managing COPD [chronic obstructive pulmonary disease] in the community, Resources for pharmacists', (Ref UK/RET/0007/16) which had the GlaxoSmithKline and NPA logo printed on the front page. A statement on the front page indicated that the booklet was written and developed by the NPA and that GlaxoSmithKline had provided funding and checked it for scientific accuracy in respect to any GlaxoSmithKline products. The booklet was designed to help community pharmacists and their teams improve the diagnosis, care and management of patients with COPD. The booklet also mentioned the Evohaler and Accuhaler devices which were GlaxoSmithKline devices for various GlaxoSmithKline medicines.

COMPLAINT

The complainant alleged that the booklet was misleading and biased when pharmacists conducted medicine use reviews (MURs) and new medicines services (NMS) with COPD patients.

The complainant referred to the statement on page 26 that:

'There are a variety of different inhaler devices available on the market for the treatment of chronic obstructive pulmonary disease (COPD) and these include: Pressurised metered dose inhalers (MDIs), Standard 'press and breathe' MDIs, Breath-activated MDIs, Dry powder inhalers (DPIs) and Soft Mist MDIs.'

The complainant also referred to a table on page 28 under a heading 'COPD inhaler devices' which referred to the Evohaler Device as an example of a standard MDI. The complainant was concerned that the reference to the 'Evohaler' device could refer not only to the Ventolin Evohaler, which was licensed for COPD, but also to the Seretide Evohaler which was not so licensed. The 'Evohaler' trade name could therefore cause confusion and acceptance that Seretide Evohaler was licensed for COPD which it was not. Community pharmacists had come across patients prescribed Seretide Evohaler off-label by both primary and secondary clinicians. This was something that should be highlighted during a MUR and NMS intervention which was not referenced in any of the MUR and NMS documentation within the booklet. It was a term that should be referenced and not freely listed as 'Evohaler' which could be linked to both Ventolin and Seretide as the device was a standard metered dose inhaler (MDI) device.

The Elipta device was not referenced in the booklet but neither were the Spiromax, NEXThaler and Forspiro devices which were all licensed for COPD. The complainant questioned the bias towards some inhaler devices that had been listed and others which had a higher % prescribing within his/her locality and not been referenced.

The complainant stated that he/she would also be writing to the NPA.

In writing to GlaxoSmithKline attention was drawn to the requirements of Clauses 3.2, 7.2, 7.3 and 9.1 of the Code.

RESPONSE

GlaxoSmithKline stated that as of 29 March 2017 the NPA confirmed that no such letter had been received.

Background, history and nature of the arrangement

The 54-page document at issue was written by the NPA for pharmacists and their teams in the community to 'Improve the diagnosis, care and management of patients with chronic obstructive pulmonary disease (COPD)'. The concept for the booklet was suggested by the NPA at a meeting with GlaxoSmithKline at the end of 2014 as the association had had experience in developing a similar booklet in diabetes which had proved to be very popular with its members.

The NPA selected one of its pharmacist writers as the 'Supplier Contact Person' as named in the contract with specific responsibility for drafting the booklet. GlaxoSmithKline agreed to fund the service. The contract also specified that the bulk of the booklets (>7,000 copies) would be sent by the NPA to its members and that GlaxoSmithKline would only take around 1000 to be given to member pharmacists of the Company Chemists' Association. GlaxoSmithKline's role in the development of the booklet was to ensure that it was in line with the requirements of the Code and more specifically to check for the scientific and medical accuracy of any GlaxoSmithKline product mentioned in the booklet. As required by the Code, the exact nature of GlaxoSmithKline's involvement was made clear on the front page of the booklet.

The booklet was reviewed and approved by the NPA's chief pharmacist who wrote the Foreword as well as certified by GlaxoSmithKline, before being sent to print. Payment for the booklet was made directly to the NPA and not to the author.

Non-promotional nature of the COPD booklet

GlaxoSmithKline submitted that the booklet was non-promotional in nature, design and content and did not refer to any GlaxoSmithKline product, nor indeed to any other pharmaceutical company's products by brand name. Where there was any mention of medicines in the booklet, they were referred to by generic name only.

As noted by the complainant, there was no mention of the Ellipta device, the respiratory device used to

deliver the majority of GlaxoSmithKline's actively promoted branded products; namely Relvar, Anoro and Incruse, as the NPA decided not to include it.

Even though the item was non-promotional in its own right it had been certified as 'Promotional' as it formed part of a suite of services which pharmacists might select to have as part of the GlaxoSmithKline Partnership Programme Agreement which provided discounts on some of the GlaxoSmithKline products. The booklets had not been proactively distributed by GlaxoSmithKline personnel and as of 29 March only the NPA had distributed them.

Alleged promotion of Seretide Evohaler in COPD

GlaxoSmithKline submitted that Seretide was not mentioned anywhere in the booklet. Its non-proprietary constituents, salmeterol and fluticasone propionate, only appeared on page 19 where they were mentioned as an example of a combined inhaled corticosteroid and then, only as the second example after formoterol plus budesonide.

The complainant correctly stated that the MDI delivery system for Seretide, Seretide Evohaler, was not licensed for use in COPD even though the dry powder (DP) delivery system, Seretide Accuhaler, was licensed (50/500mg dose only). However, the complainant incorrectly stated that Ventolin Evohaler was licensed for use in COPD, which was not so and the complainant failed to mention that Serevent Evohaler (salmeterol xinofoate) was licensed for use in patients with COPD. The choice of the Evohaler (the original inhaler device) as an example of a MDI for use in patients with COPD was therefore validated, as the Serevent Evohaler was available for use in patients with COPD since 2005.

Furthermore, the Evohaler was only mentioned in the document once, (page 29), in the third column of Table 8 entitled 'The different types of inhaler devices and instructions for their use*' and was given as an example of an MDI. The complainant failed to mention that explanation for the asterisk appeared at the end of the table on page 34, as follows:

Please note:

- ***The instructions for use in Table 8 are generic and may not be applicable to every type of inhaler listed – therefore please refer to the individual product's Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) for detailed guidance on how to use the inhaler.***
- ***The full NICE guideline "Chronic obstructive pulmonary disease: management of chronic obstructive pulmonary disease in adults in primary and secondary care, CG101" states that patients should receive training on the use of their prescribed devices and be able to demonstrate adequate technique before being prescribed the devices.***
- ***The full NICE guideline indicates that patients using inhalers should be reassessed regularly as inhaler technique can deteriorate over time***
- ***The licensed indications for inhalers vary and some may only be licensed for use in asthma and not COPD – individual product's SPCs should be referred to for more information.***
- ***If patients are unable to use their inhaler device adequately, an alternative device should be prescribed.***

GlaxoSmithKline stated that at no time was the Evohaler mentioned with Seretide nor indeed with any other GlaxoSmithKline product, nor was it referred to in the introductory section on standard metered dose inhalers (page 26).

GlaxoSmithKline therefore denied any promotion of the Seretide Evohaler for use in COPD and thus any breach of Clauses 3.2, 7.2, 7.3 and 9.1.

The choice of examples of devices

GlaxoSmithKline stated that the booklet simply gave some examples of the different types of devices and never claimed to be comprehensive in its list of all available inhalers in the UK, as a large number with new ones were introduced on a regular basis. The choice of examples was at the discretion of the NPA, which in the chapter on inhaler devices listed the following: Accuhaler, Breezhaler, Easyhaler, Handihaler, Novolizer and Turbohaler (page 26) Evohaler, Respimat (page 28), Autohaler, Easibreathe (page 29), Accuhaler, Breezhaler, Easyhaler, Handihaler, Novolizer, Turbohaler (page 30-33). The fact that these were examples was made quite clear in both the text and the table.

DuoResp Spiromax (Teva) 2014, Fostair NEXThaler (Chiesi) 2014 and Forspiro AirFluSal (Sanofi) 2015 were all more recently introduced breath actuated dry powdered inhalers (DPIs) and if included would be three more additions to the six examples already included in the booklet. The decision not to add these more recently introduced devices was not deliberate. The NPA had no specific policy to either include or exclude any specific medicines or inhalers and certainly did not have one based on the prescription/sales of inhalers at a 'local level' as cited as a criticism by the complainant. The NPA just included as examples those devices which it considered would be of most relevance to members. As the complainant correctly observed, GlaxoSmithKline's Ellipta inhaler was not mentioned in the booklet.

GlaxoSmithKline therefore denied any breach of Clauses 3.2, 7.2, 7.3 and 9.1.

GlaxoSmithKline has shared the complaint with the NPA together with its response. GlaxoSmithKline provided the NPA perspective.

Finally, GlaxoSmithKline stated that the feedback to the NPA had been extremely favourable where the booklet was being widely used by pharmacists for the benefit of patients in the community.

PANEL RULING

The Panel noted that it was possible for a company to sponsor material, produced by a third party which mentioned its own product, and not be liable under

the Code for its contents, but only if, *inter alia*, there had been a strictly arm's length arrangement between the parties. The arrangements must be such that there could be no possibility that the pharmaceutical company had been able to exert any influence or control over the final content of the material. Use of such material for a promotional purpose would mean that it was subject to the Code.

The Panel noted GlaxoSmithKline's role in relation to supporting the booklet was limited to funding and checking it for factual accuracy with respect to its own products; its content was otherwise a matter for the NPA. However GlaxoSmithKline submitted it would make the booklet available for a promotional purpose which meant that it was subject to the Code. The Panel noted GlaxoSmithKline's submission that it had not proactively distributed the booklets.

The Panel noted GlaxoSmithKline's submission that Evohaler products; Ventolin Evohaler and Seretide Evohaler, were not licensed for COPD whereas Serevent Evohaler was. The Panel noted the complainant's statement that Ventolin Evohaler was so licensed. In this regard the summary of product characteristics (SPC) for the Ventolin Evohaler stated at section 4.1, that Ventolin provided short-acting (4-6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction. The SPC then stated that it was 'particularly suitable for the relief and prevention of asthma symptoms' and that it was 'particularly valuable as relief medication in mild, moderate or severe asthma' provided that reliance on it did not delay the introduction and use of inhaled corticosteroid therapy. There was no mention of COPD in the indication section of the SPC.

The Panel noted that pages 26-38 were headed 'COPD inhaler devices', the table in question started on page 28 and was headed 'The different types of inhaler devices available and instructions for their use*'. This table listed 7 types of device providing information about the device type, examples of devices and instructions for their use. The heading to the table bore an asterisk which related to a footnote to the table which appeared as five bullet points on page 34. One bullet point stated, *inter alia*, that the licensed indications varied, and that some might only be licensed for use in asthma and not COPD – individual products' SPCs should be referred to for more information. The Panel noted that GlaxoSmithKline had requested this footnote be inserted as a correction to the draft booklet.

The Panel did not consider that it was necessarily misleading to refer simply to 'Evohaler' in Table 8 (page 28) as an example of a standard MDI device. The Panel noted that this was clearly an area of potential difficulty as demonstrated by the complainant's confusion.

The booklet included a number of loose insert 'crib sheets'. The crib sheet for a MUR in COPD did not specifically mention the need to check that medicines were licensed for COPD, nor did the crib sheet for a NMS. However, the Panel considered that this in itself was not necessarily inappropriate given that a MUR would look at all medicines prescribed. If concerned after a MUR or NMS consultation, pharmacists could query which medicines had been prescribed and why and take further action as appropriate.

The Panel did not consider that the references to Evohaler in the booklet meant that GlaxoSmithKline had promoted Seretide Evohaler for an unlicensed indication as alleged. No breach of Clause 3.2 of the Code was ruled. On balance the Panel did not consider that the reference to Evohaler as an example of a device for use in COPD was misleading as alleged. The Panel considered that it would have been helpful if the relevant footnote had appeared at the outset rather than 6 pages later where it might be read as the heading to table 9 rather than the footnote to table 8. However, the intended audience would know that not all medicines licensed for asthma were licensed for COPD. No breach of Clause 7.2 was ruled.

With regard to the lack of mention of other devices the Panel noted GlaxoSmithKline's submission that three more recent DPIs were not used as examples. The foreword which included 'Details of available COPD inhaler devices and other equipment' and the heading to pages 26-38 'COPD inhaler devices' could be seen as implying all devices would be listed. However, table 8 was clear that 'Examples of devices' were listed. The Panel considered, that, on balance, table 8 was not an unfair comparison or misleading as alleged. The Panel ruled no breach of Clauses 7.2 and 7.3.

The Panel noted its rulings above and consider that GlaxoSmithKline had not failed to maintain high standards. No breach of Clause 9.1 was ruled.

Complaint received **13 March 2017**

Case completed **28 June 2017**