NORGINE v GALEN

Prescribing policy for Laxido Orange

Norgine complained about a prescribing policy document, distributed by Galen, which detailed the process for, and the savings that could be made if patients were switched from Movicol (Norgine's product) to Laxido Orange. Laxido Orange and Movicol had the same qualitative and quantitative active ingredients; both products were used to treat faecal impaction and chronic constipation in adults and children over 12.

Norgine alleged a breach as switch services paid for or facilitated directly or indirectly by a pharmaceutical company were prohibited. It was evident that the document and associated activity related to a switch programme from Movicol to Laxido Orange assisted by third party advisors funded by Galen. Norgine further alleged that high standards had not been maintained.

The detailed response from Galen is given below.

The Panel noted that the prescribing policy document clearly encouraged readers to consider prescribing Laxido Orange where they would otherwise have prescribed Movicol. The document described the qualitative/quantitative composition of the two medicines, briefly reviewed the treatment of constipation and its cost to the NHS and noted that savings could be made by prescribing Laxido Orange instead of Movicol. The document listed a number of ways in which a switch could be implemented and detailed the savings made by such a switch in some primary care organisations (PCOs). It was noted that there were few barriers to change and that these were easily overcome. Readers were invited to contact any one of the five authors, all heads of medicines management or similar, if they had any questions regarding the switch from Movicol to Laxido Orange. The final page of the document featured the Laxido Orange prescribing information.

The Panel noted that although Galen had no editorial input into the document, it had paid the authors and had clearly regarded the material as promotional, it had been certified and included prescribing information. The company had posted the document on its trustsaver website and it had been used in calls with customers.

The Panel noted that the prescribing policy clearly promoted and encouraged readers to switch patients from Movicol to Laxido Orange; this was not unacceptable under the Code. Crucially, Galen did not provide any service to effect or facilitate that switch. Any expense or effort needed to change patients to Laxido Orange had to be borne by the health professional or PCO. The Panel noted Galen's submission that it had not helped to support or assisted any health professional to implement a switch. In that regard the Panel ruled no breach of the Code. The Panel further noted Galen's submission that there was no switch service or programme and in that regard it ruled no breach of the Code. Given these rulings, the Panel did not consider that Galen had failed to maintain high standards and so no breach of the Code was ruled.

Upon appeal by Norgine the Appeal Board noted from Galen that the prescribing policy was suggested by a paid consultant who Galen had employed for other projects. That consultant in turn, and on behalf of Galen, sourced and briefed five NHS pharmacists who were heads of medicines management, or similar, to write the document to illustrate their experience of changing prescribing from Movicol to Laxido Orange. The five pharmacists each received a one-off honorarium from Galen for their input into the document. The Appeal Board noted that Galen had reviewed the document for medical and grammatical accuracy and also to ensure its compliance with the Code.

The Appeal Board noted that the prescribing policy stated that the qualitative and quantitative active ingredients in Movicol and Laxido Orange were the same; Laxido Orange, however, was 20% less expensive than Movicol. The prescribing policy gave clear advice as to how to undertake a switch, described the strategies that the five pharmacists had found successful and the cost savings seen to date. Under a heading 'You can contact us if you have questions', readers were informed that the five pharmacists would be happy to discuss the switch and contact details were provided.

The Appeal Board noted that the supplementary information to the Code stated that switch services paid for or facilitated directly or indirectly by a pharmaceutical company were prohibited. It was further stated that companies could promote a simple switch from one product to another but not to assist a health professional to implement that switch even via a third party.

The Appeal Board queried whether the prescribing policy went beyond simply promoting a switch from Movicol to Laxido Orange. It provided detailed information of strategies to employ, the cost savings that were possible and gave the contact details of five pharmacists who would be willing to discuss the issues involved. In the Appeal Board's view there was a fine line to be drawn between simply promoting a switch and providing so much detailed information in that regard that the information in and of itself facilitated the switch. The Appeal Board recognised that NHS colleagues would talk to each other but was nonetheless concerned that contact details of five pharmacists had been provided. Galen submitted that it had neither requested nor received any feedback from the five pharmacists regarding any communication with their peers. The Appeal Board was concerned that such communication, for

which Galen might be responsible, might facilitate a switch. There was, however, no information before the Appeal Board in this regard. The Appeal Board noted that whilst Galen had provided information as contained in the prescribing policy document, it had not actively assisted any health professional to switch patients from Movicol to Laxido Orange.

The Appeal Board noted its comments above and considered that the prescribing policy was on the limits of acceptability and so, on balance, it upheld the Panel's rulings of no breach of the Code. The appeal was unsuccessful.

Norgine Pharmaceuticals Ltd complained about a document headed 'Prescribing policy: Laxido Orange (macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride) as a relatively straightforward QIPP [quality, innovation, productivity and prevention] saving opportunity – the process and the results' (ref PMR-APR-2013-0093) distributed by Galen Limited. The document detailed the savings that could be made if patients were switched from Movicol (Norgine's product) to Laxido Orange. Laxido Orange and Movicol had the same qualitative and quantitative composition of active ingredients; both products were used to treat faecal impaction and chronic constipation in adults and children over 12.

COMPLAINT

Norgine alleged that the prescribing policy was in breach of Clauses 18.1 and 18.4 which prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company. The company further alleged a breach of Clause 9.1 as high standards had not been maintained.

In inter-company correspondence, Norgine noted that on the document at issue, it was stated that the prescribing policy activity had been commissioned and funded by Galen. Norgine considered that it was evident that the document and associated activity related to a switch programme from Movicol to Laxido Orange assisted by third party advisors (eg a head of medicines management, at a local, clinical commissioning group) who had been funded by Galen.

RESPONSE

Galen explained that Laxido Orange contained the same active ingredients as Norgine's product, Movicol and had been approved as a generic medicinal product of Movicol. However, as Laxido Orange was 20% less expensive to buy than Movicol in both 20 and 30 pack sizes, a number of primary care organisations/clinical commissioning groups (PCOs/CCGs) had already changed from prescribing Movicol to prescribing Laxido Orange as it benefitted the NHS in terms of medicine acquisition cost savings and maintained patient care.

Galen submitted that a prescribing policy which shared the experience of changing prescribing from Movicol to Laxido Orange was suggested by a contracted consultant in January 2013. Galen was interested in the suggestion and subsequently agreed the following:

- the consultant would source information from managers who had undertaken such a change in prescribing policy in their region and were willing to share their experience
- Galen would have no editorial input into the content of the document apart from review for medical and grammatical accuracy and to ensure compliance with the Code
- an accurate, honest and balanced document that complied with the Code was to be prepared
- an honorarium (at fair market value) would be paid to the contributing authors by Galen, via the consultant who compiled the document
- engagement of the authors by the consultant/ Galen would not be an inducement to prescribe, supply, administer, recommend, buy or sell any Galen product.

The consultant sourced five independent managers who agreed to share their experience of changing prescribing from Movicol to Laxido Orange due to the cost savings offered to the NHS. Before the medicines managers were approached for their input into the prescribing policy, four trusts had completed a change in prescribing from Movicol to Laxido Orange in their respective regions, while the remaining fifth trust had initiated the process to do so. This was reflected in the following wording which appeared in the prescribing policy:

> 'The undersigned authors have all successfully completed, or are completing, the switch from Movicol to Laxido Orange.'

Agreements, subsequently put in place between Galen and the authors, all stated that Galen's engagement of the authors was not an inducement to prescribe, supply, administer, recommend, buy or sell any Galen product. The authors were paid an honorarium at fair market value for their contribution to the prescribing policy document.

The first draft of the prescribing policy that Galen saw was in early February 2013. However, the contracted consultant and authors did not deem that the document was ready to be entered into the official review process until April. The document then went through a number of draft versions where Galen only reviewed it for medical and grammatical accuracy. Galen had no editorial input into the design and content of the document. This was made clear in the prescribing policy by the statement: 'Galen has had no editorial input apart from review for medical and grammatical accuracy and to ensure compliance with the ABPI Code of Practice'.

The final draft of the document was entered into Galen's approval system on Friday, 10 May, with subsequent certification by two Galen Code signatories on the same day.

The Laxido Orange prescribing policy document was posted as a resource on the Galen trustsaver website (www.trustsaver.co.uk), had been used in calls with customers by Galen health service managers and had been disseminated at company meetings.

Galen noted Norgine's allegation of a breach of Clauses 18.1 and 18.4 and that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated:

> 'Clauses 18.1 and 18.4 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. 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 are seen as companies in effect paying for prescriptions and are unacceptable.'

As noted to Norgine in a letter of 6 August, the prescribing policy document was not part of any switch service/programme. It was simply a retrospective, standalone document through which a number of heads of medicines management shared their best practice experience of changing prescribing of Movicol to Laxido Orange, with their peers. There was no switch service or programme.

Galen stated that it had not at any time helped to support or assisted any health professional to implement a switch. As was permitted under the Code, Galen has used the document to help promote a simple change in prescribing from Movicol to Laxido Orange. The document illustrated that such a change in prescribing was relatively straightforward and could be achieved quickly, that in reality there were no significant barriers to change, and that significant recurring savings could be realised.

In summary, the prescribing policy was a peer-to-peer report which shared best practice on PCOs'/CCGs' experiences in changing prescribing. Galen submitted that it had had no influence over the design and content during drafting and noted that the briefing detailed that the document should be balanced and include negative information if required eg on barriers to change. As stated above, before being contacted by the Galen consultant regarding writing the prescribing policy, four of the five authors had fully completed a change in prescribing from Movicol to Laxido Orange, while the remaining author had initiated the process to do so. Also, a written agreement was in place with the five authors before commencement of the services which clearly stated that their involvement in the prescribing policy was not an inducement to prescribe, supply, administer, recommend, buy or sell any Galen product. Galen had no editorial input into the design and content of the document.

Galen denied a breach of Clauses 18.1 and 18.4. Subsequently, there was also no breach of Clause 9.1. On the contrary, Galen had maintained high standards at all times and its involvement in the production of this document had been carried out in line with the Code and had been made clear and unambiguous. This was illustrated by the clear, prominent declaration statement 'This Prescribing Policy has been commissioned and funded by Galen Limited. Galen has had no editorial input apart from review for medical and grammatical accuracy and to ensure compliance with the ABPI Code of Practice' that appeared on the prescribing policy. This made the extent of Galen's involvement and lack of influence over the material totally clear, in line with Clause 9.10.

Galen considered that the complaint was an attempt by Norgine to discredit an effective and compliant campaign that promoted a medicine which benefitted the NHS in terms of cost savings, and maintained patient care.

PANEL RULING

The Panel noted that the prescribing policy document clearly encouraged readers to consider prescribing Laxido Orange where they would otherwise have prescribed Movicol. The document described the qualitative/quantitative composition of the two medicines, briefly reviewed the treatment of constipation and its cost to the NHS and noted that savings could be made by prescribing Laxido Orange instead of Movicol which would facilitate the QIPP agenda of the NHS. The document listed a number of ways in which a switch could be implemented and detailed the savings made by such a switch in some PCOs. It was noted that there were few barriers to change and that these were easily overcome. Readers were invited to contact any one of the five authors, all heads of medicines management or similar, if they had any questions regarding the switch from Movicol to Laxido Orange. The final page of the document featured the Laxido Orange prescribing information.

The Panel noted that although Galen had no editorial input into the document, it had paid the authors and had clearly regarded the material as promotional, it had been certified in accordance with the Code and it included prescribing information for Laxido Orange. The company had posted the document on its trustsaver website and it had been used in calls with customers.

The Panel noted that the prescribing policy clearly promoted and encouraged readers to switch patients from Movicol to Laxido Orange. As noted in the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, this was not unacceptable under the Code. Crucially, Galen did not provide any service to effect or facilitate that switch. Any expense or effort needed to change patients to Laxido Orange had to be borne by the health professional or PCO. The Panel noted Galen's submission that it had not helped to support or assisted any health professional in implementing a switch. In that regard the Panel ruled no breach of Clause 18.1. The Panel further noted Galen's submission that there was no switch service or programme and in that regard it ruled no breach of Clause 18.4. These rulings were appealed by Norgine.

Given its rulings above, the Panel consequently ruled no breach of Clause 9.1. This ruling was appealed by Norgine.

APPEAL FROM NORGINE

Norgine was extremely disappointed with the Panel ruling and questioned the rationale behind the decision. Norgine challenged the Panel's statement that '… Galen did not provide any service to effect or facilitate that switch' particularly with reference to the Code's clarity on the prohibition of switch programmes; the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated 'Clauses 18.1 and 18.4 prohibit switch services paid for or **facilitated directly or indirectly** by a pharmaceutical company whereby a patient's medicine is simply changed to another.' (emphasis added by Norgine).

Norgine alleged that, at the very least, the prescribing policy clearly indirectly facilitated a switch where patients were simply switched from Movicol to Laxido Orange in breach of Clauses 18.1 and 18.4. Galen had indeed indirectly facilitated the switch for clinicians.

Norgine noted that the supplementary information cited above further 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 …'** (emphasis added by Norgine).

Norgine alleged that Galen had assisted prescribers to implement that change as by its admission the prescribing policy facilitated communication between prescribers who had switched and those who had not and provided information and guidance that they would have otherwise had to seek independently to begin to affect that change. Specifically, information on who had experience of such switches and where and how to contact them, and crucially, practical help with planning a switch programme and help with addressing practical issues. The policy detailed the potential methods for effecting the switch and provided specific detailed information on which tools to use to effect the switch in specific regions of the country, it gave detailed advice on overcoming barriers to a switch and provided contact details of named pharmacists who effectively acted as 'facilitators' and who were engaged specifically to provide this information to potential prescribers – if this was not facilitation (at least indirectly) what was?

Norgine noted that Galen had initiated this item, paid for its creation and paid the pharmacists that contributed to it. As such, Norgine alleged these pharmacists were effectively working on behalf of Galen and speaking with its voice, given that they had endorsed the prescribing policy which was clearly promotional and included prescribing information. Norgine found Galen's contention that it had no input into the content of the item difficult to believe given the timescales involved and how the item was finally approved for use.

Norgine noted the time frame for the development of the prescribing policy as provided by Galen:

- The prescribing policy was first 'proposed' in January 2013
- First draft reviewed by Galen on 7 February
- Official review on 10 April
- A number of draft versions where Galen 'only reviewed for medical and grammatical accuracy'
- Final draft reviewed and approved by two Galen signatories on the same day of the review on 10 May.

Norgine alleged that as the review process was effectively almost completely done 'off-line', and that only the final version was uploaded to Galen's copy approval system on the day of certification, it strained credibility to suggest that Galen had no editorial input into the design or content of the document (including addition of prescribing information) from first draft on 7 February to the final version on 10 May (nearly 4 months), where several versions were reviewed (with no evidence provided by Galen of these versions and who provided input into these reviews).

Norgine alleged that Galen's contention that it was approached by a contracted consultant in January 2013 to initiate the prescribing policy was irrelevant. A contracted consultant was a Galen representative for the duration of the contract and the decision to go ahead with the item remained Galen's alone.

Norgine alleged that the prescribing policy was clearly in breach of Clauses 9.1, 18.1 and 18.4 of the Code.

COMMENTS FROM GALEN

Galen noted that Norgine disagreed with the Panel's statement that 'Crucially, Galen did not provide any service to effect or facilitate that switch' and again noted that Clauses 18.1 and 18.4 of the Code prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company.

Galen agreed that the Code clearly prohibited switch programmes. However, Galen reiterated that the prescribing policy was not part of any switch service/ programme; it was a retrospective, standalone document through which, a number of heads of medicines management shared, with their peers, their experience of changing the prescribing of Movicol to Laxido Orange. There was no switch service or programme.

Galen noted that Norgine had also quoted the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, which stated '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.' Galen submitted that in compliance with this, it had used the prescribing policy to help promote a simple change in prescribing from Movicol to Laxido Orange. The document illustrated that such a change in prescribing was relatively straightforward

and could be achieved quickly, that in reality there were no significant barriers to change and that significant recurring savings could be realised.

Norgine had alleged that Galen had assisted prescribers to implement a change in prescribing as the prescribing policy facilitated communication between prescribers who had switched and those who had not and further provided information and guidance that they would have otherwise had to seek independently to begin to affect that change. Specifically, information on who had experience of such switches and where and how to contact them, and crucially, practical help with planning a switch programme and help with addressing practical issues.

Galen submitted that furthermore Norgine had also claimed that the prescribing policy had provided contact details of named pharmacists who effectively acted as 'facilitators' and who had been engaged specifically to provide this information to potential prescribers. Galen submitted that it had never helped to support or assisted any health professional to implement a 'switch'. This included the provision of any financial support or practical assistance. As acknowledged by the Panel, 'Any expense or effort needed to change patients to Laxido Orange had to be borne by the health professional or PCO'.

Galen submitted that the prescribing policy was written by five independent managers who agreed to share their experience of changing from Movicol to Laxido Orange due to the cost savings offered to the NHS. The managers were only engaged by Galen to write the prescribing policy. The inclusion of their names and contact details so that they could address any questions from their peers in relation to their best practice experience of changing prescribing of Movicol to Laxido Orange, was their own decision and entirely reasonable.

Galen submitted that it had never requested or received any reports or feedback from the authors regarding any communication with their peers. It was untrue to claim that these managers acted as 'facilitators' of a switch service or programme that would be prohibited under the Code and wrongly questioned the credibility of these key, experienced NHS pharmacists.

Galen noted that Norgine queried the independence of the document and cited the timelines provided by Galen with regard to the review and approval process. Galen submitted that this was a new issue which Norgine had never questioned previously and that the time over which the document was drafted was irrelevant.

Galen submitted that the prominent and accurate declaration wording contained in the prescribing policy made the extent of its involvement and lack of influence over the material totally clear, in line with Clause 9.10. Galen had been transparent in this regard and firmly disputed the claim that its involvement was any more than declared; had that been the case, the authors would not have allowed their names to be associated with the document. Laxido Orange was a key and successful product for Galen in the UK; the company's continued good relationship with customers and all matters of Code compliance were of utmost importance to it.

Galen submitted that with regard to Norgine's final point, the reference to the contracted consultant in Galen's response above was completely relevant as the PMCPA had requested full details of Galen's involvement in producing and distributing the prescribing policy and Galen had thus answered the PMCPA's question as to who initiated the material.

In summary, Galen submitted that the Panel's rulings in this case were completely unequivocal and Norgine had not provided any new and relevant information in relation to its complaint. The fact remained that the prescribing policy was not part of a switch service or programme. As acknowledged by the Panel, any expense or action required to achieve this lay with the individual health professionals or PCOs and the Laxido Orange prescribing policy was not in breach of Clauses 18.1 and 18.4 of the Code and consequently not in breach of Clause 9.1.

FINAL COMMENTS FROM NORGINE

Norgine did not consider that Galen's comments above added anything new to the discussion in this case.

APPEAL BOARD RULING

The Appeal Board noted from the representatives of Galen that the prescribing policy at issue was suggested to Galen by a paid consultant who it had employed for other projects. That consultant in turn, and on behalf of Galen, sourced and briefed five NHS pharmacists who were heads of medicines management, or similar, to write the document to illustrate their experience of changing prescribing from Movicol to Laxido Orange. Four of the pharmacists had already completed the switch process; the other had yet to do so. The five pharmacists each received a one-off honorarium from Galen for their input into the prescribing policy document. In the Appeal Board's view, although the concept, content and design of the prescribing policy had come from consultants working on behalf of the company, Galen was wholly responsible for the document, in the same way as it would be responsible for any other piece of promotional material. The Appeal Board noted that Galen had reviewed the document for medical and grammatical accuracy and also to ensure its compliance with the Code.

The Appeal Board noted that the prescribing policy stated that the qualitative and quantitative active ingredients in Movicol and Laxido Orange were the same; Laxido Orange, however, was 20% less expensive than Movicol. The prescribing policy gave clear advice as to how to undertake a switch and included a list of bullet points which described the strategies that the five pharmacists had found successful; a table showed the mix of strategies employed by each of the pharmacists in their respective PCOs. A second table detailed the cost savings seen to date in each PCO and there was a

short discussion on barriers to change. Under a heading 'You can contact us if you have questions', readers were informed that the five pharmacists would be happy to discuss the switch from Movicol to Laxido Orange and their contact details (email and telephone) were stated.

The Appeal Board noted that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated that:

> 'Clauses 18.1 and 18.4 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. 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 are seen as companies in effect paying for prescriptions and are unacceptable.'

The Appeal Board noted the content of the prescribing policy and queried whether it went beyond simply promoting a switch from Movicol to Laxido Orange. It provided the reader with detailed information of strategies to employ, the cost savings that were possible and gave the contact details of five pharmacists who would be willing to discuss the issues involved. In the Appeal Board's view there was a fine line to be drawn between simply promoting a switch and providing so much detailed information in that regard that the information in and of itself facilitated the switch. The Appeal Board recognised that NHS colleagues would talk to each other but was nonetheless concerned that contact details of five pharmacists had been provided. Galen submitted that it had neither requested nor received any feedback from the five pharmacists regarding any communication with their peers. The Appeal Board was concerned that such communication, for which Galen might be responsible, might facilitate a switch. There was, however, no information before the Appeal Board in this regard. The Appeal Board noted that whilst Galen has provided information as contained in the prescribing policy document, it had not actively assisted any health professional in implementing a switch for patients on Movicol to Laxido Orange.

The Appeal Board noted its comments above and considered that the prescribing policy was on the limits of acceptability and so, on balance, it upheld the Panel's rulings of no breach of Clauses 18.1 and 18.4 and consequently upheld the ruling of no breach of Clause 9.1. The appeal was unsuccessful.

Complaint received **21 October 2013**

Case completed **15 January 2014**