

ANONYMOUS NON-CONTACTABLE v GALEN

Promotion of Laxido

An anonymous, non-contactable complainant complained about the promotion of Laxido by Galen at the recent Scottish Prescribers Association meeting. Laxido (macrogol plus electrolytes) was a laxative.

The complainant stated that his/her team recently returned from the meeting and had come to the collective view that misleading activity should be brought to the PMCPA and MHRA's attention. The complainant stated that he/she complained because of Galen's persistent activity repeated year after year. As an example, the complainant provided a photograph of a Laxido exhibition panel from an earlier meeting which he/she alleged contained a misleading comparison which referred to what was then an erroneous category M change which was reversed within months of the comparison. The complainant stated that the Galen representative consistently referred to potential savings with Laxido.

The complainant was concerned that Galen had brought the industry into some reputational challenge with continued misleading claims about potential future savings because Laxido Orange was more expensive than CosmoCol Orange and, even more troubling, Laxido Natural was more expensive than CosmoCol Plain in like for like and direct comparison.

The complainant noted that NHS Scotland used over 80% adherence to Laxido as a brand so the promotional materials reflecting a saving potential of several million pounds was clearly a claim that was not sustainable given the changes in Laxido pricing always in the upward trend since 2015 (sic).

The complainant submitted that the Galen representative seemed to have no clear understanding about the structure of NHS Scotland and the way in which the devolved health economy operated.

The representative assured the complainant that there was no need to switch to a lower price product (CosmoCol), as Galen would offer a rebate to cover the differential which was not permitted under standing financial rules in NHS Scotland. The complainant referred to a consistent misrepresentation of the company's pricing and not just Laxido. Examples were provided.

The complainant provided details of four substantive points, three with regards to misleading potential savings and a fourth that alleged Galen had suggested that a competitor company would not be afloat in 2016/17.

The detailed response from Galen is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints

would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information. The Panel noted the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened.

With regard to the allegation regarding the alleged erroneous category M change which had been reversed, the Panel noted that the complainant had provided no details. The Panel considered that without further information it was impossible for the Panel to consider this matter. In any event, the Panel noted Galen's submission that the category M change was only apparent in the Drug Tariff for England and Wales. The Panel ruled no breach of the Code.

The Panel noted the allegations about the cost saving claims and statements made by representatives about the rebate to cover the differential cost of using Laxido rather than switching to a lower price product. Representatives at the meetings had denied making the claims alleged.

The Panel noted Galen's submission that Laxido Natural was discontinued in September 2009. Whilst Laxido Orange was more expensive than CosmoCol Orange-flavoured and CosmoCol orange, lemon and lime-flavoured, Laxido Orange was less expensive than CosmoCol Lemon and Lime flavoured.

There was no claim that Laxido Orange was the cheapest product only that savings could be made compared to using the market leading brand. According to Galen, the cost of Laxido Orange had not increased since July 2014.

The complainant had not provided any materials regarding the potential savings of several million pounds. If Scotland was using 80% Laxido Orange then savings would depend on what was used for the remaining 20%. From Galen's submission it was not CosmoCol Orange.

On the material provided by the complainant the Panel was uncertain what the basis was for the alleged lack of understanding the Galen representative had about the NHS Scotland health economy.

The complainant had not provided any evidence about either the alleged rebate Galen offered to continue use of Laxido instead of changing to CosmoCol nor the price promise for Calceos.

Noting the totality of material before it and the complainant's burden of proof, the Panel did not consider that the complainant had established that misleading comparisons about cost savings and the comments about the rebate had been made. No breach of the Code was ruled.

With regard to the allegation that Galen had disparaged one company by referring to it as not being afloat in 2016/17, the Panel noted the differences in the parties' accounts. The complainant had provided no evidence and Galen had denied that its staff had made such statements. The Panel decided that on the balance of probabilities the complainant had not proved his/her complaint in this regard and therefore ruled no breach of the Code.

The Panel did not consider that the complainant had provided evidence to show that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

An anonymous, non-contactable complainant complained about the promotion of Laxido by Galen Ltd at the recent Scottish Prescribers Association meeting. Laxido (macrogol plus electrolytes) was a laxative.

COMPLAINT

The complainant stated that his/her team recently returned from the meeting and had come to the collective view that misleading activity should be brought to the PMCPA and MHRA's attention referring to the Code and the Blue Book. The complainant stated that he/she complained because of Galen's persistent activity repeated year after year. As an example, the complainant provided a photograph of a Laxido exhibition panel from an earlier meeting which he/she alleged contained a misleading comparison which referred to what was then an erroneous category M change which was reversed within months of the comparison. The complainant stated that the Galen representative consistently referred to potential savings with Laxido.

The complainant was concerned that Galen had brought the industry into some reputational challenge (Clause 2, disrepute) with the continued misleading claims about potential future savings. The complainant alleged claims about potential future savings were misleading as Laxido Orange was more expensive than CosmoCol Orange and, even more troubling, Laxido Natural was more expensive than CosmoCol Plain in like for like and direct comparison.

The complainant noted that NHS Scotland used over 80% adherence to Laxido as a brand so the promotional materials reflecting a saving potential of several million pounds was clearly a claim that was not sustainable given the changes in Laxido pricing always in the upward trend since 2015 (sic).

The complainant submitted that the Galen representative seemed to have no clear

understanding about the structure of NHS Scotland and the way in which a devolved NHS Scotland health economy operated.

The representative assured the complainant that there was no need to switch to a lower price product (CosmoCol), as Galen would offer a rebate to cover the differential which was not permitted under standing financial rules in NHS Scotland. On further analysis of prescribing data and records of previous engagements with Galen representatives the complainant referred to a consistent misrepresentation of the company's pricing and not just Laxido. For example with Calcium and Vitamin D product (Calceos), Galen gave a price promise which was quietly dropped when other lower price products came to the complainant's and Galen's attention for example Acrete D3 (Internis' product) and theiCal D3 (Stirling Anglian's product). A promise not kept.

The complainant submitted that his/her substantive points were:

- 1 Galen showed a misleading picture of potential savings year on year. When a saving was made it remained the benchmark for the following months and year. Laxido in 2016 would have to show decrease in price vs Laxido 2015. The fact was that Laxido Orange had increased in price in 2016 and not delivered savings in contrast to CosmoCol Orange and CosmoCol Plain (the two like-for-like comparison products in that range). The complainant noted that there was a small amount of use of Movicol Lemon and Lime which was again more expensive than CosmoCol Lemon and Lime.
- 2 In order to claim savings for NHS Scotland, Galen should [not] refer to the direct comparison ie like-for-like in flavour and indeed the true reflection of the spend in the NHS Scotland osmotic laxative use and make the comparison relevant to those with whom they were engaging ie NHS Scotland which was a devolved part of the wider UK infrastructure with devolved budgets for prescribing as well as no prescription charge. The complainant noted the current picture of prescribing for NHS in respect of osmotic laxatives. In summary, the complainant queried how savings could be claimed and whether relevant savings should be based on the Scottish health economy and the comparisons made on a like-for-like basis?
- 3 The complainant submitted that Laxido Natural was more expensive than CosmoCol Plain. Laxido represented a cost increase and not a saving to NHS Scotland (and no doubt NHS England, NHS Wales, and NHS Northern Ireland). The complainant alleged this misled the NHS and with consistent variance in Laxido pricing in 2016, he/she was confused as to which price was the settled price for the product at the same time as others remained stable?
- 4 The complainant also noted that one of his/her colleagues had suggested that Galen had been

slagging off of a competitor company, suggesting that it would not be afloat in 2016/17.

The complainant stated that the above added up to a lowering of trust and confidence not only in Galen but more widely in the industry over misleading pricing, rebates, and comparisons that were not like-for-like.

When writing to Galen the Authority asked it to bear in mind Clauses 2, 7.2, 7.3 and 8.1.

RESPONSE

Galen submitted that it took these issues extremely seriously and was happy to cooperate fully, however, it questioned the validity of the complaint due to both its content and somewhat coincidental timing with Case AUTH/2892/11/16 and a letter it had recently received from Internis Pharmaceuticals. The company's concerns would become clear when reviewing its response. Plus there were numerous references to Stirling Anglian's products and one to Internis Pharmaceuticals.

In addition, Galen stated that the complaint was extremely vague and lacked clear evidence upon which Galen was able to respond, however, it endeavoured to respond fully and within the spirit of each comment provided.

Galen was disappointed and thought it was unusual for a complainant to make allegations about a meeting without providing any details of the meeting, date or location.

The complainant alleged that Galen's activity was misleading and had been persistent year after year. Galen had not received any complaint of this nature before and in the absence of specific information investigated its presence at this annual event.

Galen attended the Scottish Prescribing Association meetings in 2014, 2015 and 2016. It provided details about the dates and venues for the meetings, which Galen staff attended and the banner stands used. In 2014 the Laxido Orange (PMR-OCT-2014-0288) stand was used and in 2015 and 2016 the Trustsaver (PMR-MAY-2015-0150) stand was used. Photographs were provided.

Galen stated that the representatives who attended these meetings were interviewed and were asked a number of questions including the use of rebates to cover differential costs of Laxido Orange and CosmoCol Orange, other price promises regarding Calceos and discussions about Laxido Natural. All the representatives stated that these topics were not discussed. No representative agreed that they had ever disparaged a competitor company or suggested that it would not be around in 2016/17.

With regard to the photograph provided by the complainant (Galen pointed out that there was no date) and the alleged use of old materials, Galen assumed the reference to an earlier meeting was either 2014 or 2015 but the complainant was not specific.

Galen stated that the photograph provided by the complainant suggested the meeting was 4 November 2014. The materials used were approved in October 2014 and so were not out of date. The claims were based on the cost of Laxido Orange and the Drug Tariff at that time and were correct both for the UK and more specifically Scotland.

Galen questioned whether it was usual for a health professional to keep such a photograph for so long, to be able to find it and not being able to validate the date, time and location. It was also strange that a more recent example was not presented.

With reference to the complainant's mention of an 'erroneous Cat M change' Galen wondered what the Department of Health's reaction would be to that claim as Galen did not believe it could be substantiated. Indeed this change was not Galen's interpretation. It should, however, be noted that this 'erroneous change' was only apparent in the Drug Tariff for England and Wales.

Galen submitted that the banner stands used at the 2015 and 2016 meetings were compliant.

With regard to the complainant's statement that Galen made continued misleading claims about future potential savings but again provided no evidence, Galen agreed that it had made claims regarding savings vs drug tariff costs and market-leading brands. The savings were only achievable if health professionals prescribed and continued to prescribe Laxido Orange by brand.

Galen noted that the Trustsaver banner stand used in 2015 and 2016 made no reference to specific products and clearly supported the concept of Trustsaver and opened the door for further dialogue, as well as providing information regarding the website where specific information was available. As a result, it was unclear how this was misleading or anything other than statements of fact. In addition, the details of the Trustsaver website were clearly prominent and invited health professionals to look for more information. Trustsaver was introduced by Galen in 2010 and since then, the same underlying claims had been consistently made and accepted by the target audience.

Based upon previous cases, and indeed all products being approved by the MHRA as generics to the brand originator, all products within the CosmoCol range were like-for-like with the brand originator Movicol, as was Laxido Orange.

Laxido Orange (orange flavour) was introduced in 2008 and was the first branded generic for Movicol (lemon & lime flavour). Both products had the same qualitative and quantitative active ingredients. The market, Norgine and Case AUTH/2494/3/12 (Norgine v Galen, Trustsaver campaign) accepted that the Trustsaver campaign was simply about changing prescribing from one medicine to its less expensive generic equivalent and Laxido Orange had been accepted as being a generic equivalent of Movicol. In Case AUTH/2494/3/12 Galen demonstrated that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas.

In addition, a Prescribing Policy document (which was reviewed in Case AUTH/2644/10/13 Norgine v Galen and was no longer used by Galen) stated:

- Using Eclipse Live as an audit tool, only 0.007% of patients registered on the Isle of Wight who have been prescribed Laxido Orange have been prescribed MOVICOL®* subsequently.
- Issues such as differing taste, effectiveness of previous medication or a health care professional having recommended the previous product have not represented a significant barrier to change for the authors;
- Many [primary care organisations] PCOs have already undertaken the switch successfully.'

The statement regarding Laxido Natural was factually incorrect – Laxido Natural was last shipped from Galen on 1 May 2009 and the Dictionary of Medicines and Devices changed the flag to discontinued on 16 September 2009.

The complainant's claim of 80% adherence to Laxido as a brand was not supported by any details as to how the figure was obtained and from what date.

Galen stated that the complainant's statement 'Laxido pricing always in the upward trend since 2015' was irrefutably incorrect and raised concerns regarding the complainant's motives and indeed questioned the validity of the complaint.

The NHS Dictionary of Medicines and Devices (dm+d) system showed that the price of Laxido Orange 30s had not changed since 7 July 2014 and on that date the price was reduced from £5.34 to £4.27. There had been no pricing changes 'since the 2015'.

In order to understand the current impact of using Laxido Orange vs generic macrogol in Scotland, Galen looked at the latest prescription cost analysis (PCA) data for Scotland (an extract of adult Macrogol on a like-for-like basis was provided). If all Laxido Orange had been prescribed as generic Macrogol then the gross ingredient cost would have been £5,716,016.16 vs £2,712,251.43, representing a saving of approximately £3,000,000 by prescribing Laxido Orange.

The current drug tariff price for generic macrogol prescriptions in Scotland was £9 vs £4.27 for Laxido Orange.

Savings were only realised with continued branded prescribing and indeed further savings could be realised if Laxido Orange was prescribed vs both Movicol and generic prescriptions.

Galen stated that the Trustsaver banner stand used in 2015 and 2016 made no reference to specific products and clearly supported the concept and opened the door for further dialogue, and provided information regarding the website where specific information was available. It did not provide specific banners for particular regions within the UK, as within Scotland and England there were differences at each primary care organisation level (CCG within England and Health Boards in Scotland), however, Galen provided

the opportunity for each individual PCO to discuss specific savings models. These were offered by both the sales team and via the Trustsaver website.

The complainant specifically referred to 'CosmoCol' being a lower price than Galen's product, whilst earlier in the complaint the complainant tried to distinguish between the products in the range. Galen submitted this was misleading as CosmoCol as a brand had 3 different flavours with a different pricing policy across them. In December 2016 the prices of CosmoCol were orange, lemon and lime-flavoured, 20 = £2.75 and 30 = £3.95; orange-flavoured, 20 = £2.75 and 30 = £3.95; lemon and lime-flavoured, 20 = £3.56 and 30 = £5.34 and unflavoured, 30 = £3.95.

The price of Laxido Orange was 20 = £2.85 and 30 = £4.27.

Galen submitted that clearly CosmoCol Lemon and Lime was more expensive than Laxido Orange, and, according to the Prescription Cost Analysis from Scotland for 2015/16 by value CosmoCol Lemon and Lime represented the highest 'gross ingredient cost' out of all CosmoCol preparations in 2015/16: £1,481 for Lemon and Lime vs £1,322 for Orange and £389 for Orange, Lemon and Lime.

Galen stated that the allegation regarding references to 'rebates' was factually incorrect. The representatives who had attended this meeting over the last 3 years categorically denied making such a statement. In any case, any rebate would need the approval of the managing director who confirmed that this option had NEVER been on the table and would NEVER be approved.

With regard to the price promise and competitor pricing with regard to Calceos, Galen submitted that its product Calceos was marketed as the least expensive calcium/vitamin D3 chewable tablet. Accrete D3 was not the same form, ie it was not a chewable tablet. This was clear on all materials. The market was complex in the sense that most products differed in their quantitative ingredients. On 4 June 2014, the Galen sales team was instructed to stop promoting Calceos. There was a price promise for Calceos which offered savings until 2014 vs leading calcium/Vitamin D3 chewable tablets. Calceos maintained this position and thus the allegation that Galen did not keep this promise was factually incorrect.

Galen was committed to remaining competitive in the branded calcium/vitamin D market. Should the price of Adcal D3 or Calcichew D3 Forte drop to below the price of Calceos, then the price of Calceos would be lowered to at least match this price. The price reduction would occur within six months and the price pledge was in place until at least 2014.

The Stirling Anglian website stated that theiCal-D3 was launched Q4 2014. Galen had never received any complaint on this subject from anyone else in the UK.

Galen stated that the alleged '... misleading picture of potential savings year on year When a saving

is made this remains the benchmark for the following months and year' was extremely broad and there was no specific point to comment on. Galen denied it had, or was showing, a misleading picture of potential savings year-on-year. Within this complaint there were no details regarding what the 'misleading picture' was.

Laxido Orange 30s had not changed price since 7 July 2014, and on that date the price was reduced from £5.34 to £4.27. Laxido Orange had not increased in price in 2016.

Savings were only realised with continued branded prescribing and indeed further savings could be realised if Laxido Orange was prescribed vs both Movicol and generic prescriptions.

The Trustsaver banner used in 2015 and 2016 made no reference to specific products and clearly supported the concept and opened the door for further dialogue and provided information regarding the website where specific information was available.

CosmoCol Orange was introduced in 2014.

The allegation that 'Laxido represents a cost increase and not a cost saving' was factually incorrect. According to the Prescription Cost Analysis from Scotland for 2015/16, £868,972.03 of Movicol and £573,580.20 of generic macrogol compound was dispensed and, as shown below, Movicol was more expensive than Laxido as was the Scottish Drug Tariff for generic prescriptions.

The statement regarding 'others remaining stable in pricing in 2016' was factually incorrect. The Movicol Lemon and Lime 30s showed the price increased on the 2 May 2016 from £7.35 to £7.72.

With regard to the allegation that a competitor company was 'slagged off', Galen submitted it had investigated this point as fully as possible on the little information to substantiate the meeting date, meeting location or representative's name. However, assuming it referred to the meeting in 2014, representatives who attended these meetings since 2014 categorically denied any 'slagging off' of any competitor. Indeed, all representatives had exemplary records within Galen and had been with the company for many years with no complaints from either a competitor pharmaceutical company or a health professional. Anyone with any concerns regarding Galen's employees or promotional campaigns should raise them immediately and not 2 years later. There was no evidence of a breach of Clause 8.1.

Galen submitted that the allegation regarding a lowering of trust and confidence over misleading pricing, rebates and comparisons that were not like-for-like carried no weight based on all the content above. Having conducted a thorough investigation Galen could see no evidence regarding breaches of Clauses 7.2, 7.3, 8.1 and therefore Galen had not brought the industry into disrepute. At the time of use, the materials were accurate, balanced and certainly not misleading and there was no evidence that the sales team were disparaging competitors in

any way. This was in contrast to the complainant, be it a health professional or competitor, who presented incorrect information designed to mislead and therefore disparage Galen.

PANEL RULING

The Panel noted that the complaint had been copied to the MHRA and referred to the Blue Book. The PMCPA could only consider cases in relation to the requirements of the Code.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information. The Panel noted the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened.

With regard to the allegation regarding the alleged erroneous category M change which had been reversed, the Panel noted Galen's submission that the banner stand showed the cost of Laxido Orange and the macrogol Drug Tariff prices as at October 2014 and was used in November 2014. The complainant had provided no details about the alleged erroneous category M change. The Panel noted its comments above that the complainant had the burden of proof and was uncontactable. The Panel considered that without further information it was impossible for the Panel to consider this matter. In any event, the Panel noted Galen's submission that the category M change was only apparent in the Drug Tariff for England and Wales. The Panel ruled no breach of Clause 7.2.

The Panel noted the allegations about the cost saving claims and statements made by representatives about the rebate to cover the differential cost of using Laxido rather than switching to a lower price product. Representatives at the meetings had denied making the claims alleged. The Panel noted that the Trustsaver banner stand used in 2015 and 2016 bore the prominent claim 'Trustsaver Quality brands with the saving of generics'. A subheading referred to 'Cost savings' in yellow font and a subsequent bullet point read 'Significant drug acquisition cost savings vs market-leading brands'. No medicines were named. The Panel considered that given the banner and therapeutic area, it was not unreasonable to assume that cost savings were discussed by the representatives at the meeting. The Panel did not know what other material was available at the stand.

The Panel noted Galen's submission that Laxido Natural was discontinued in September 2009. Whilst Laxido Orange was more expensive than CosmoCol Orange-flavoured and CosmoCol orange, lemon and lime-flavoured, Laxido Orange was less expensive than Cosmocol Lemon and Lime flavoured.

There was no claim that Laxido Orange was the cheapest product only that savings could be made compared to using the market leading brand. According to Galen, the cost of Laxido Orange had not increased since July 2014.

The complainant had not provided any materials regarding the potential savings of several million pounds. If Scotland was using 80% Laxido Orange then savings would depend on what was used for the remaining 20%. From Galen's submission it was not CosmoCol Orange.

On the material provided by the complainant the Panel was uncertain what the basis was for the alleged lack of understanding the Galen representative had about the NHS Scotland health economy.

The complainant had not provided any evidence about either the alleged rebate Galen offered to continue use of Laxido instead of changing to CosmoCol nor the price promise for Calceos.

Noting the totality of material before it and the complainant's burden of proof, the Panel did not consider that the complainant had established that

misleading comparisons about cost savings and the comments about the rebate had been made. No breach of Clauses 7.2 and 7.3 was ruled.

With regard to the allegation that Galen had disparaged one company by referring to it as not being afloat in 2016/17, the Panel noted the differences in the parties' accounts and its comments above in this regard. The complainant had provided no evidence and Galen had denied that its staff had made such statements. The complainant had provided very few details and no evidence to support his/her allegations. The Panel decided that on the balance of probabilities the complainant had not proved his/her complaint in this regard and therefore ruled no breach of Clause 8.1.

The Panel did not consider that the complainant had provided evidence to show that Galen had brought discredit upon or reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

Complaint received **30 November 2016**

Case completed **13 January 2017**
