

ANONYMOUS NON-CONTACTABLE v GALEN

Trustsaver website

An anonymous, non-contactable complainant, who appeared to work in a clinical commissioning group (CCG), complained about Galen's Trustsaver website regarding potential savings with Galen's laxative Laxido (macrogol plus electrolytes).

The complainant noted that the site had a defined claim of potential savings of tens of millions of pounds across the UK health economy but queried whether this reflected England, Wales, Scotland and Northern Ireland all of which had devolved health economies.

The complainant noted that the site only had a saving comparison with the most expensive macrogol and not a like for like comparison and raised a number of questions.

The complainant stated that the CCG had been a large user of Laxido and was misled by the Trustsaver site and the claims which were clearly not going to be made in this budget cycle.

The complainant requested that the Trustsaver site with its retrospective claims on savings be taken down and that instead it illustrated prospective savings. These claims applied to all brands and not just Laxido; the complainant noted that the CCG also used other Galen products such as steripoules and diltiazem.

The complainant asked that Galen reflect the diverse nature of the health service in the devolved economies and split potential savings into each country. He/she asked the PMCPA to ask Galen to try to reflect savings of/or costs in year and not to seek to mislead the GP population. The complainant alleged that Galen could and would bring itself and the industry into disrepute.

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 complainant's concerns with regard to the claim that 'Trustsaver has potentially saved the NHS over £36 million since it launched in 2010' which was qualified by the use of an asterisk with the explanation immediately beneath that 'The savings estimate refers to drug acquisition costs. It has been calculated using PCA data for the Trustsaver products and reflected the theoretical difference in costs, had 100% of prescriptions been for the market-leading competitor instead (excludes

latest product additions and includes a past Trustsaver product)' and was referenced to data on file. The Panel did not consider it was necessarily misleading to give savings as one figure to the NHS rather than for each devolved nation. More detail could be obtained by using the personalised cost saving calculator and inputting relevant data. In addition, the Panel noted Galen's submission that all countries in the UK shared the same pricing policies for all Trustsaver products. It thus ruled no breach of the Code.

With regard to the cost comparison being against the market leader only, which the complainant referred to as the most expensive macrogol and not showing the prices of other available products, the Panel considered that it was clear that the website showed comparisons with the market leading brands. The Panel noted that Laxido Natural had been discontinued and therefore it was not misleading to omit it. In the circumstances it was not misleading to use potential retrospective savings for illustration based on average annual usage. There was no indication that using Laxido Orange was the cheapest option. Only that savings would be made compared to using the identified market leading brand. In addition, the Panel noted that if switches to Galen's product were made in year 1 the comparison with the cost of Laxido and the market-leading brand in year 2 were somewhat artificial. Further savings might be made by changing from a Galen product to an alternative, less expensive, medicine albeit not a market leader. It was not necessarily misleading to select products for comparison, it would depend on the basis of the selection and whether this had been made clear. The Panel did not consider it was necessarily misleading to use retrospective comparisons in relation to savings compared with the use of the market leading brand rather than potential prospective savings.

The Panel considered that the basis of the comparisons was clear and the complainant had not shown on the balance of probabilities that the material was misleading as alleged. The Panel ruled no breach of the Code.

The Panel was concerned that the page of the website which set out product information about Laxido Orange claimed '45% savings with Laxido Orange' as a heading to a graph which compared the other major macrogol 3350 plus electrolytes brand. This was followed by 'Did you know the NHS currently spends more than £67 million per year on prescribing osmotic laxatives' and the claim 'make significant drug acquisition cost savings by prescribing Laxido Orange by brand'. These might give the impression that the savings were more than just a comparison with the market leading brand. The introduction to the Trustsaver portfolio

at the top of the page referred to 'drug acquisition cost savings vs market-leading brands' whereas a prominent highlighted banner at the bottom of the page referred to significant drug acquisition cost savings by prescribing Laxido Orange by brand. There was no mention of this being in comparison to market-leading brands. On balance, the Panel considered that given the content of the website and the context of the page itself, although this page could and should be improved, it was not in itself misleading. No breach of the Code was ruled.

The Panel noted its rulings above. It did not consider that the complainant had shown on the balance of probabilities 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, who appeared to work in a clinical commissioning group (CCG), complained about Galen Limited's Trustsaver website.

COMPLAINT

The complainant noted that for some time, he/she had been targeted by members of his/her CCG about potential savings with Galen's laxative Laxido (macrogol plus electrolytes). The complainant stated that this was not unusual as the CCG strove to have cost efficient and quality prescribing. The complainant was reminded of a visit by a Galen representative who asked him/her to look at the Trustsaver website which was not an issue until the complainant noted the contents.

The complainant noted that the site had a defined claim of potential savings of tens of millions of pounds across the UK health economy but queried whether this reflected England, Wales, Scotland and Northern Ireland all of which had devolved health economies. The complainant asked if the potential saving should be split into each country within the union.

The complainant noted that the site only had a saving comparison with the most expensive macrogol and not a like for like comparison and raised the following questions:

- 1 Should the comparison not be on a like for like basis eg Laxido Orange vs CosmoCol and other orange preparations? This would mean in reality that Laxido actually cost the NHS quite a large amount of cash going forward.
- 2 Should Laxido Natural not be listed on the site and compared with other preparations such as CosmoCol plain? This again would show that going forwards as well as in the past a huge cost consequence for the NHS would be seen.
- 3 Should the comparisons actually not be retrospective but be based on potential prospective savings year on year ... reflecting the NHS budgeting cycle?

The complainant stated that the feedback from a successful switch to Laxido from all preparations

showed that 15% of patients asked to switch back to Movicol Lemon and Lime. Now that the potential savings had been reviewed, it had been decided to change Movicol Lemon and Lime to CosmoCol Lemon and Lime and all generically prescribed unflavoured macrogol to a cost effective plain preparation.

The complainant requested that like for like comparisons were made to reflect the very real cost consequence associated with Laxido in year; the CCG was not focussed on savings it might have realised rather savings it might make in year and prospectively.

The complainant stated that the CCG had been a large user of Laxido and was misled by the Trustsaver site and the claims which were clearly not going to be made in this budget cycle, disappointing its GPs.

The complainant requested that the Trustsaver site with its retrospective claims on savings be taken down and that instead it illustrated prospective savings. These claims applied to all brands and not just Laxido; the complainant noted that the CCG also used other Galen products such as steripoules and diltiazem.

The complainant asked that Galen reflect the diverse nature of the health service in the devolved economies. He/she asked the PMCPA to ask Galen to try to reflect savings of/or costs in year and not to seek to mislead the GP population. The complainant alleged that Galen could and would bring itself and the industry into disrepute.

In writing to Galen the Authority asked it to bear in mind the requirements of Clauses 2, 7.2 and 7.3 of the Code.

RESPONSE

Galen submitted that it took these issues extremely seriously and was happy to cooperate fully. The complaint was anonymous which made it difficult to gain clarity as to the exact nature of the concerns. It was not possible to verify the assumption that the complainant worked in a CCG although Galen accepted the website was likely to be accessed by primary care organisation (PCO) medicines management.

The Trustsaver website (<http://www.trustsaver.co.uk/home>) had been available since 2010 and the underlying principles had remained the same. Through Galen's branded generic products, savings could be made versus branded market leaders. Since this date, Galen had had only three complaints regarding Trustsaver claims, the first was settled by the PMCPA in Galen's favour (Case AUTH/2494/3/12 Norgine v Galen), the second was resolved by inter-company dialogue with Stirling Anglian Pharmaceuticals and in the third, Galen was currently engaged in inter-company dialogue with Internis Pharmaceuticals. No complaints, except possibly this one, had been made by a health professional.

The Trustsaver concept had been consistent in its message of offering 'significant drug acquisition cost savings vs. market-leading brands' and as a result was not misleading health professionals in claiming to include all comparator preparations available.

Galen responded to each point of the current complaint in turn:

1 'The site has a defined claim of potentially saving tens of millions £££ across the UK health economy. I am not sure if this reflects England, Wales, Scotland and Northern Ireland all of which have devolved health economies My first question is should this not be split into each country within our union?'

Galen submitted that the Trustsaver website was United Kingdom specific (.co.uk) and clearly stated at the top of every page that it was intended for 'UK HCPs only'. All countries within the Union shared the same pricing policies for all the Trustsaver products. In addition, by referring to the NHS and not specifically NHS England, NHS Wales, NHS Scotland or NHS Northern Ireland, Galen submitted that it was clear regarding the territories concerned, although this did not seem to be a concern or complaint but a question from the complainant.

In addition, Galen provided the facility for more personalised saving models by individual PCO or by using an on-line calculator.

As a result Galen submitted that the statement was unambiguous and clear and therefore not in breach of Clause 7.2.

2 'Should the comparison not be on a like for like basis e.g. Laxido Orange Vs CosmoCol and other Orange preparations?'

Galen submitted that Laxido Orange (orange flavour) was introduced in 2008 and was the first product approved as a generic of Movicol (lemon & lime flavour). Both products had the same qualitative and quantitative active ingredients, the same pharmaceutical form and were indicated for the same purpose. In Case AUTH/2494/3/12 (Norgine v Galen, Trustsaver campaign) it was accepted that the Trustsaver campaign was simply about changing prescribing from one medicine to its less expensive generic equivalent, and Laxido Orange was, and continued to be, accepted as 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 some areas.

As had been successfully and clearly demonstrated over the years since its launch, Trustsaver was based on savings vs market-leading brands (ie the most widely prescribed). This was clearly set out at the top of the Trustsaver homepage and as other brands such as the named Cosmocool were insignificant in terms of market share, Galen did not compare against it.

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

In addition, a Prescribing Policy Document (which was reviewed in Case AUTH/2644/10/13 Norgine v Galen, Prescribing Policy for Laxido Orange) (which was no longer used by Galen) stated the following:

- 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 PCOs have already undertaken the switch successfully.'

Interestingly, it seemed the complainant might also have misunderstood the competitors and their differences. For example, both Laxido Orange and Movicol had consistent pricing across their preparations, ie Movicol unflavoured, lime and lemon and chocolate flavoured products all share the same pricing policy, whilst Cosmocool had a different pricing strategy depending upon the flavour. CosmoCol Orange had a 3% market share in England as shown by PCA data from August 2016 and so clearly was not a market-leading brand.

Galen submitted that the Trustsaver website was clear by stating 'significant drug acquisition cost savings vs. market-leading brands' and, as a result, Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and so was therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

3 'Should Laxido Natural not be listed on the site and compared with other preparations such as CosmoCol plain?'

Galen explained that 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 Trustsaver website was clear by stating 'significant drug acquisition cost savings vs. market-leading brands' and as a result was not misleading health professionals in claiming to include all preparations available and not in breach of Clauses 7.2 or 7.3.

Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and was therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

4 'Should the comparisons actually not be retrospective but be based on potential prospective savings year on year ... reflecting the NHS budgeting cycle.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing and competitor pricing might change, this could merely inflate or deflate any savings calculation and potentially lead to more claims of providing misleading information.

The website provided a calculator allowing the user to input their own annual average usage, as well as providing a slider tool to show the % of scripts

the users believed they could convert to a given Trustsaver product.

Case AUTH/2494/3/12 accepted the savings figures were illustrative and in accordance with Clause 7.2 and, as good practice, Galen had tried to be as accurate as possible in an attempt to give the best indication of the potential savings available.

As a result, Galen submitted the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

5 'In reality the feedback from our successful switch to Laxido from all preparations showed a proportion of patients 15% who asked to switch back to Movicol Lemon and Lime at that time. Now that we have looked again at potential savings we have decided to change Movicol Lemon and Lime to CosmoCol Lemon and Lime and all generically prescribed macrogol unflavoured macrogol to change to a cost effective plain preparation.'

Galen accepted that not everyone would accept the change to Laxido Orange and this could be for a variety of reasons. Conversions had been made in a number of areas with a high degree of acceptance as the complainant acknowledged. Galen had not tried to portray that a conversion of 100% would occur and this was clearly stated in an open and transparent manner. Again, this point was reviewed in Case AUTH/2494/3/12.

As previously stated, the website provided a calculator allowing the user to input their own annual average usage as well as providing a slider tool to show the % of scripts the users believed they could convert to a given Trustsaver product.

In addition, the Prescribing Policy Document (which was reviewed by the PMCPA Case AUTH/2644/10/13 Norgine v Galen, Prescribing Policy for Laxido Orange) (which was no longer used by Galen) stated the following:

- 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 PCOs have already undertaken the switch successfully.'

6 'In short I ask that like for like comparisons are made reflecting the very real cost consequence associated with Laxido in year we are not focussed on savings we may have realised rather savings we may make in year and prospectively.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing

this could merely inflate any savings calculation and thereby potentially lead to more claims of providing misleading information.

The website provided a calculator allowing the user to input their own annual average usage as well as providing a slider tool to show the % of scripts the users believed they could convert to a given Trustsaver product.

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 scripts.

As a result Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

7 'I feel that we have been large user of Laxido and feel misled by the trustsaver site and the claims which are clearly not going to be made in this budget cycle, disappointing our GPs.'

Galen stated it was not clear exactly what the concerns were here. However, the Trustsaver website was not misleading and not in breach of either Clauses 7.2 or 7.3.

8 'Can you ask Galen to take down their site "trustsaver" with retrospective claims on savings and illustrate prospective savings? These claims apply to all brands and not just Laxido again we are users of other galen products such as steripoules and diltiazem.'

Galen submitted that prospective, by its very nature, was a forecast and hence unlikely to be accurate. As many of the markets were growing this would merely inflate any savings calculation and potentially lead to more claims of providing misleading information.

Galen's generic Saline Steripoules was removed from the website on 18 October 2016 for commercial reasons. However, at the time of removal the product had a NHS list price (£13.50) – significantly less than both the drug tariff (£16.91 Nov 2016) and the other market-leading competitor product on sale in the UK (£21.70).

As a result Galen submitted that the comparison was unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

9 'Can you ask Galen to reflect the diverse nature of our Health services in devolved economies?'

As previously stated, Galen did not see what additional benefit this provided, as the website was UK specific and all countries within the Union shared the same pricing policies for all the Trustsaver products. In addition, as stated clearly on the website, Galen provided the facility for more personalised saving models by PCO or by using an on-line calculator.

10 'Can you ask Galen to try and reflect savings of/or or [sic] and costs in year and not seek to mislead our GP population?'

Galen was unsure what was meant by this request but strongly denied that it had misled any health professional.

As previously submitted, the comparisons were unambiguous, clear and on a 'like-for-like' basis, and therefore not misleading and not in breach of either Clauses 7.2 or 7.3.

Galen totally refuted the allegation that it had brought the industry into disrepute.

PANEL RULING

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 that there had been a previous complaint about Trustsaver, Case AUTH/2494/3/12 where no breaches of the Code had been ruled. There were differences between the complaints.

Turning now to the current complaint the Panel noted the complainant's concerns with regard to the claim that 'Trustsaver has potentially saved the NHS over £36 million since it launched in 2010' which was qualified by the use of an asterisk with the explanation immediately beneath that 'The savings estimate refers to drug acquisition costs'. It has been calculated using PCA data for the Trustsaver products and reflects the theoretical difference in costs, had 100% of prescriptions been for the market-leading competitor instead (excludes latest product additions and includes a past Trustsaver product) and was referenced to data on file. The complainant was concerned that the potential savings should be split into each country ie instead of covering the UK, provide figures for Northern Ireland, Scotland, Wales and England. The Panel did not consider it was necessarily misleading to give savings as one figure to the NHS rather than for each devolved nation. More detail could be obtained by using the personalised cost saving calculator and inputting relevant data. The cost calculator could also show savings if a particular percentage of scripts were changed from the market leader brand to a Galen Trustsaver product. In addition, the Panel noted Galen's submission that all countries in the UK shared the same pricing policies for all Trustsaver products. It thus ruled no breach of Clauses 7.2 and 7.3 in this regard.

With regard to the cost comparison being against the market leader only, which the complainant referred to as the most expensive macrogol and

not showing the prices of other available products, the Panel considered that it was clear that the website showed comparisons with the market leading brands. The Panel noted that Laxido Natural had been discontinued and therefore it was not misleading to omit it. In the circumstances it was not misleading to use potential retrospective savings for illustration based on average annual usage. There was no indication that using Laxido Orange was the cheapest option. Only that savings would be made compared to using the identified market leading brand. In addition, the Panel noted that if switches to Galen's product were made in year 1 the comparison with the cost of Laxido and the market-leading brand in year 2 were somewhat artificial. Further savings might be made by changing from a Galen product to an alternative, less expensive, medicine albeit not a market leader. It was not necessarily misleading to select products for comparison, it would depend on the basis of the selection and whether this had been made clear. The Panel did not consider it was necessarily misleading to use retrospective comparisons in relation to savings compared with the use of the market leading brand rather than potential prospective savings.

The Panel considered that the basis of the comparisons was clear and the complainant had not shown on the balance of probabilities that the material was misleading as alleged. The Panel ruled no breach of Clauses 7.2 and 7.3.

The Panel was concerned that the page of the website which set out product information about Laxido Orange claimed '45% savings with Laxido Orange' as a heading to a graph which compared the other major macrogol 3350 plus electrolytes brand. This was followed by 'Did you know the NHS currently spends more than £67 million per year on prescribing osmotic laxatives' and the claim 'make significant drug acquisition cost savings by prescribing Laxido Orange by brand'. These might give the impression that the savings were more than just a comparison with the market leading brand. The introduction to the Trustsaver portfolio at the top of the page referred to 'drug acquisition cost savings vs market-leading brands' whereas a prominent highlighted banner at the bottom of the page referred to significant drug acquisition cost savings by prescribing Laxido Orange by brand. There was no mention of this being in comparison to market-leading brands. On balance, the Panel considered that given the content of the website and the context of the page itself, although this page could and should be improved it was not in itself misleading. No breach of Clauses 7.2 and 7.3 were ruled.

The Panel noted its rulings above. It did not consider that the complainant had shown on the balance of probabilities 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