NORGINE v GALEN

Trustsaver campaign

Norgine alleged that Galen's Trustsaver campaign materials, namely a website, leavepiece and advertisements, contained misleading and exaggerated claims about cost savings which could be achieved by switching from certain branded market leaders (including Norgine's Movicol) to certain named Galen products.

Galen's detailed response is given below.

Norgine alleged that the cost savings calculated in an interactive 'map of savings' section of the website were misleading because, *et al*, the one year savings could only happen if 100% of patients taking the branded products were switched simultaneously to the Galen products. This would not happen. Further, the claims did not make it clear that the savings stated were only possible in year one.

The Panel noted that the Trustsaver campaign was designed to show prescribers how much they could save if they prescribed Galen's branded generic medicines instead of the more expensive branded market leaders. The campaign was simply about switching from one medicine to its less expensive generic equivalent; the only variable factor would be the acquisition cost.

The Panel noted that the homepage of the Trustsaver website stated that Galen had a range of products that offered significant savings against the market leading brands. Readers could access an interactive map of savings whereby they could find out the total potential one year savings if Galen's medicines Flotros, Laxido Orange and Calceos were prescribed instead of the current market leading brands. In the same block of text which explained how to use the interactive map, the readers were invited to click on a link which took them to a comprehensive explanation of assumptions and calculations. In all cases it was assumed that all prescriptions would be switched to the Galen products.

The Panel considered that although a 100% switch was unlikely, and those accessing the website would understand that to be so, it would, nonetheless, be seen as a goal in order to maximise any savings. The interactive map of savings clearly referred to 'Total *potential* one year savings …' (emphasis added). The Panel noted that the map of savings referred to 'one year savings' not 'year one savings'. In that regard, the Panel did not consider that an instantaneous switch was necessary; the year could start at the point when all patients had been switched. The Panel considered that in the context of demonstrating to prescribers the potential magnitude of savings that could be made in one year by prescribing Galen products, the map of savings was not misleading. The underlying assumptions were sufficiently clear. No breach of the Code was ruled.

Norgine alleged that a section of the website entitled 'Savings Calculator' exaggerated the savings that could be achieved and noted that again the calculated savings relied on an unrealistic 100% switch to Galen's product from day one.

The Panel noted that by accessing the savings calculator readers could calculate how much they would save if they switched 100% of their prescriptions from brand leaders to the equivalent Galen branded generic medicines. The Panel noted that users had to input their annual average use of the brand leader in order to calculate the average annual saving. Assumptions and calculations were clearly stated. The Panel considered that although a 100% switch was unlikely, and the target audience would understand that to be so, it would nonetheless be seen as a goal in order to maximise any savings. In that regard the Panel considered that it would be impossible to design a tool which would, with complete accuracy, predict the percentage of prescriptions that would be switched and thus calculate the potential savings. The Panel considered that within the context of demonstrating to prescribers the potential magnitude of savings that could be made in one year by prescribing a specific Galen product instead of the market leader, the savings calculator was not misleading. No breach of the Code was ruled.

Norgine noted that the leavepiece included a claim that by using three specified Galen products, an average size primary care organisation (PCO) could potentially save £270k/year. Norgine stated that as the £270k was so prominently presented, and without qualification, there appeared to be little uncertainty in the figure. To achieve this saving 100% of patients would have to be switched to Galen products overnight which would never happen. Norgine alleged that the claim was misleading and exaggerated.

The Panel noted that the leavepiece was entitled 'Master the art of saving'. Readers were informed that the Galen Trustsaver collection of six branded generics offered significant savings against current market-leading brands. The claim at issue referred to three Galen medicines (Laxido Orange, Calceos and Flotros) and stated that the average-sized PCO could potentially save £270k per year by adopting these medicines. Readers were invited to visit the Trustsaver website to calculate potential savings locally. The Panel again noted the assumption and calculations involved and the limitations thereof together with its comments above and considered that in the context of informing prescribers about

the potential magnitude of savings that could be made in one year, the leavepiece was not misleading. No breach of the Code was ruled.

Norgine noted that the advertisements included the claim 'It may look like only a few pounds saved but to the NHS it could mean £45 million' and alleged that as above, this national figure for savings was unobtainable and misleading. In reality, 100% of NHS prescribers would not switch 100% of patients to Galen medicines on day one and continue that prescribing pattern for 12 months. Norgine alleged that the claim was exaggerated.

The Panel noted that the advertisements showed two people in what appeared to be an art gallery. Three 'paintings' were Galen packshots. In the middle of the 'gallery' there was a bigger-than-life-size pile of pound coins which one of the people was studying. The headline read 'It may look like only a few pounds saved but to the NHS it could mean £45 million'. The advertisement explained that Galen products offered significant savings against the current market-leading brands. The calculations and assumptions for the claimed savings were stated and as before they relied upon a 100% switch to relevant Galen medicines. As above the Panel noted the limitation of the assumptions together with its comments above and considered that in the context of informing prescribers about the potential magnitude of savings that could be made, the advertisements would not mislead the target audience. No breach of the Code was ruled.

Norgine considered that the Trustsaver campaign was seriously flawed. It singularly failed to maintain high standards and warranted consideration of a breach of Clause 2.

The Panel noted its rulings above and consequently considered that Galen had not failed to maintain high standards. No breach of the Code was ruled. The Panel did not consider that the Trustsaver campaign was such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

Norgine Pharmaceuticals Ltd complained about the Trustsaver campaign run by Galen Limited. Norgine alleged that the associated website, leavepiece (ref PMR-Sept-2011-0359) and advertisements in Prescriber and Nurse Prescriber (refs PMR-Feb-2012-0076 and PMR-Feb-2012-0070) contained misleading and exaggerated claims about cost savings which could be achieved by switching from certain branded market leaders (including Norgine's product Movicol) to certain named Galen products.

By way of background Norgine noted that supplementary information to Clause 7.2 stated: 'The economic evaluation of medicines is a relatively new science. Care must be taken that any claim involving the economic evaluation of a medicine is borne out by the data available and does not exaggerate its significance. To be appropriate as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate …'. This was sensible guidance, as most prescribers had little or no training in health economics, and as such they might be less able to evaluate promotional cost savings claims based on economic comparisons of medicines than comparative safety or efficacy claims.

Norgine submitted that in a climate of relentless downwards pressure on NHS expenditure, it was particularly important not to mislead payers and prescribers by exaggerated claims of cost savings available by switching from one product to another. In their willingness to save money whenever and however possible, prescribers and payers were likely to be less critical of cost saving claims.

The Trustsaver campaign was based on the principle that as Galen's branded generic products were generally less expensive than the branded market leaders such as Movicol, savings could be achieved by switching to the Galen product. Norgine was, however, seriously concerned that Galen had misled prescribers as it specified very precise cash savings that could be achieved at a practice level, a primary care trust/clinical commissioning group (PCT/CCG) level and even nationally.

The Trustsaver campaign centred on the claim that medicines budgets would be reduced at all levels (practice, PCT/CCG and national) and fundamentally consisted of a budget impact analysis (BIA). Either the prescriber filled in details directly on the Trustsaver website which then calculated budget impact (savings), or aggregated savings data was produced to claim savings on a PCT/CCG level or nationally in the leavepiece and the journal advertisements respectively.

BIA was frequently used in the economic evaluation of medicines, eg to allow payers to calculate, prior to launch, what impact the introduction of a new medicine would have on their local budgets. Norgine submitted that it was important that BIA was conducted as accurately as possible to give payers and prescribers the best possible information and referred to some of the key recommendations in best practice guidelines.

Norgine submitted that calculations should look at a realistic estimate as to how the new product might penetrate the market compared with an established product. A properly conducted BIA would produce a number of scenarios for market penetration and present the budget impact of each. For example a sound model would be able to compute the budget impact in scenarios in which product A took 20%, 30%, 40%, 50%, 60%, or 70% etc of the sales of product B over a given period of time. A model that assumed 100% market penetration without scenario analyses of anything less was therefore unrealistic and invalid, as Norgine believed was the case with the Trustsaver campaign.

By way of background, Galen explained that the Trustsaver concept was introduced just over two years ago with the principle of offering a portfolio of quality medicines which could potentially benefit the

NHS in terms of cost savings, while maintaining patient care. In the time that it had been running, no health professional had complained to Galen about it. Galen noted Norgine's view that potential cost savings claims used in Trustsaver materials consisted of a BIA and that this had not been carried out properly. Galen submitted that its Trustsaver campaign was not a BIA and in that regard noted that a BIA was:

> 'an essential part of a comprehensive economic assessment of a health-care technology and is increasingly required, along with cost-effectiveness analysis (CEA), before formulary approval or reimbursement. The purpose of a BIA is to estimate the financial consequences of adoption and diffusion of a new health-care intervention within a specific health-care setting or system context given inevitable resource constraints.' (Mauskopf *et al* 2007).

Galen explained that one of the core principles of the Trustsaver campaign was that the medicines included in the portfolio were not new ones or in a new class. Each product was a quality product, containing well established active ingredients. In the potential cost savings claims the Trustsaver products were being compared 'like-for-like' with the branded market leader based on the number of equivalent packs used and the current list prices, eg Laxido Orange was the generic equivalent of Norgine's market-leading brand, Movicol but was clearly less expensive to buy than Movicol. This cost differentiation had not been challenged by Norgine. The potential cost savings claims in the Trustsaver materials were simple and straightforward cost calculations based on the purchase price of the products. The basis of the claims was made clear throughout the materials and they did not mislead the target audience.

In Galen's view, Norgine had attempted to complicate the issue by presenting the potential cost savings claims as a BIA. Laxido was not a new or unproven class of medicine and Galen had not presented these potential cost saving claims as a BIA and never referenced it as a BIA.

A Trustsaver website

1 Interactive map of savings

COMPLAINT

Norgine noted that the Trustsaver website (www.trustsaver.co.uk) contained a section entitled 'Map of Savings'. By selecting a region on the map (for example Camden) the calculator informed the user that:

> 'The potential one year saving if Flotros, Laxido Orange and Calceos are prescribed instead of other current market leading brands' will be £140,524.

Norgine alleged that for a number of reasons this claim was misleading in breach of Clause 7.2.

- The one year savings could only happen if 100% of patients taking the brand leading products were switched to the listed Galen products; this would never happen in reality. Some prescribers might be unwilling to switch some or all patients to the Galen brands and some patients might be unwilling to be switched to the Galen brands if they were happy with their current treatment.

- In order for savings of this magnitude to be achieved, 100% of patients would need to switch to Galen brands all at the same time on day one. Logistically this could never happen as some patients would need to visit their prescriber for a change to take place, and new prescriptions would need to be produced for patients on repeat prescriptions, so there would be some considerable period of phasing whilst the change to the Galen brands occurred.

- Potential savings might be achieved over the first year by switching to a less expensive medicine, but the claim did not make clear that the saving was only possible for the first year. If less expensive products were continued for subsequent years nowhere near the initial saving could be achieved.

- The saving figure was very precise (to the last £1) and therefore implied a high degree of precision in the savings calculation, when in fact this was far from the truth as BIA was not a precise science.

- No scenario analyses were presented for anything other than 100% switching.

RESPONSE

Galen submitted that the Trustsaver campaign had evolved and changed and the map of savings was not part of the current website. It was retired on 27 March 2012 due to the changing structure of the NHS.

When it existed, the map of savings used IMS data to calculate the savings available in various UK regions. The assumptions and calculations for the map of savings contained considerable and detailed information on how the savings figures were obtained for each product (Flotros, Calceos and Laxido Orange). This could be accessed via a very clear and prominent direct link.

The fact that the savings figures presented were based on a 100% conversion was made very clear in the assumptions and calculations. Indeed when the savings figure for each region was presented, the statement that accompanied it read: 'Total potential one year saving if Flotros, Laxido Orange and Calceos are prescribed instead of the other current market leading brands'.

As noted in inter-company dialogue, prescribers, budget managers and medicines management teams were all highly qualified, intelligent and experienced, and would understand that any conversion would not be instantaneous and so savings would not be realised immediately. They would also know what approximate percentage conversion they were likely to realise in their own localities. Galen had not tried to portray that a 100% conversion would definitely occur or that any conversion would happen instantaneously.

Norgine had also raised a point that these savings were only available for one year ie that if less expensive products were continued for subsequent years, nowhere near the initial saving could be achieved. However, this was not the case. The savings figures were based on what would be spent on Trustsaver products vs the market-leading brands. This held true for any subsequent years provided that prices remained constant; the assumptions made it clear that the calculations were based on NHS list prices at a certain time point. It could be argued that the savings figures vs the market-leading brands might even increase in subsequent years. Trustsaver was an evolving, changing campaign and the costs were monitored and updated when they happened, thus providing accurate potential cost savings.

It was accepted that the savings figures presented were, illustrative. However 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. Norgine's point about a BIA not being a precise science was not valid as this was not based on BIA as previously explained.

Similarly Norgine's complaint that no scenario analyses were presented for anything other than 100% conversion was invalid as the map of savings was not based on BIA for the reasons outlined above. Galen submitted that it had openly and transparently made it clear that the savings figures were based on a 100% conversion. Galen knew that the NHS communicated cost minimisation in varying degrees but 100% was regularly used as the initial starting point and newsletters and guidance from different NHS primary care organisations (PCOs) (an example was provided) referred to a 100% conversion target for various medicines and so basing potential savings on a 100% conversion was not unusual for illustrative purposes.

Galen denied that the Trustsaver map of savings was in breach of Clause 7.2.

PANEL RULING

The Panel noted that the Trustsaver campaign was designed to show prescribers how much they could save if they prescribed Galen's branded generic medicines instead of the more expensive branded market leaders. Galen's products were not new medicines and so in that regard the Panel did not consider that Norgine's reference to BIA was relevant. Manskopf *et al* stated that the purpose of a BIA was to estimate the financial consequences of adoption and diffusion of a new healthcare intervention within a specific healthcare setting or system context given inevitable resource constraints. The Panel noted that the Trustsaver campaign was simply about switching from one medicine to its less expensive generic equivalent – it was not about the use of a new healthcare intervention. The only variable factor would be the acquisition cost.

The Panel noted that the homepage of the Trustsaver website stated that Galen had a range of products that offered significant savings against the market leading brands. Readers could access an interactive map of savings whereby they could find out the total potential one year savings if Galen's medicines Flotros, Laxido Orange and Calceos were prescribed instead of the current market leading brands. Although the interactive map was no longer in use it had been a feature of the Trustsaver website when Norgine had submitted its complaint. In the same block of text which explained how to use the interactive map, the readers were invited to click on a link which took them to a comprehensive explanation of assumptions and calculations. In all cases it was assumed that all prescriptions would be switched to the Galen products.

The Panel considered that although a 100% switch was unlikely, and those accessing the website would understand that to be so, it would, nonetheless, be seen as a goal in order to maximise any savings. In that regard the Panel noted the NHS newsletter provided by Galen. The interactive map of savings clearly referred to 'Total *potential* one year savings …' (emphasis added). The Panel noted that the map of savings referred to 'one year savings' not 'year one savings'. In that regard, the Panel did not consider that an instantaneous switch was necessary; the year could start at the point when all patients had been switched. The Panel considered that in the context of demonstrating to prescribers the potential magnitude of savings that could be made in one year by prescribing Galen products, the map of savings was not misleading. The underlying assumptions were sufficiently clear. No breach of Clause 7.2 was ruled.

2 Laxido Orange Savings Calculator

COMPLAINT

Norgine noted that the website contained a section entitled 'Savings Calculator' which enabled users to select a specific Galen product and enter the average annual usage of a specified brand, and the website would calculate the 'average annual saving'. For example, users were invited to enter their annual average usage of Movicol 20 and 30 packs in order to calculate 'Average Annual Saving'. No guidance was given on this page about how this variable should be sourced. If users selected Laxido Orange, the screen entitled 'Laxido Orange Savings Calculator' opened. Users then entered the annual average usage of Movicol (for example 1000 units of Movicol 30) and the website calculated an 'Annual average saving' of

£1,340.00. The following assumptions and calculations were listed below the savings calculator:

'1 The NHS list price of Laxido Orange is £3.56 per 20 sachet pack and £5.34 per 30 sachet pack.

2 Equivalent Laxido Orange cost is calculated by switching the annual usage entered by brand and pack size directly to Laxido Orange at the equivalent pack size.

3 The potential savings calculated are based on the annual usage entered by brand, and assume that all units are switched to the equivalent pack of Laxido Orange.

4 All flavours of MOVICOL are priced at the prices listed above.'

Norgine submitted that the key assumption here was that all units were switched to the equivalent pack of Laxido Orange. As noted above, the scenario of 100% switch from Movicol to Laxido Orange from day one was unrealistic. Also the savings figure referred to was a maximum annual saving not an average annual saving as claimed. Norgine alleged that this section of the website exaggerated the savings which could be achieved in breach of Clause 7.2.

RESPONSE

Galen submitted that the Laxido Orange Savings Calculator was a simple tool, essentially the same as a desk calculator within the website, designed to indicate to users the cost savings that they could potentially make, based on the figures that they entered into the calculator. Users clearly must enter the 'Average annual usage' themselves, which in turn calculated the average annual saving. Users would know how to source a figure for their own 'average annual usage'.

Galen stated that one of the assumptions stated was that 'The potential savings calculated are based on the annual usage entered by brand, and assume that all units are switched to the equivalent pack of Laxido Orange'. It was clear that 'all units' referred to all of the units inputted by the user. The user could be in no doubt that the calculation was based on all units being converted. These were the possible savings based on the current list prices and reflected the fact that Laxido Orange was 20% less expensive than Movicol. This cost differentiation had not been challenged by Norgine.

Galen submitted that the fact that the user inputted the usage figures themselves was a key point. This meant that the savings calculator was very flexible as it allowed a variation in usage to be entered. Users would know what approximate degree of a conversion they were likely to realise in their own respective localities, and so could adjust their figures accordingly. As with the Map of Savings, Galen had not tried to portray that a 100% conversion would definitely occur or that any conversion would happen instantaneously. Galen submitted that data on file demonstrated that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas. This could be shared with the Panel if requested. Therefore presenting potential savings figures based on a 100% conversion in an open and transparent manner was not unreasonable.

The savings figure referred to could not be a maximum annual saving as claimed by Norgine, as users only entered their 'average annual usage'. To be a maximum savings figure, users would need to input their maximum annual usage.

Galen submitted that this section of the website did not exaggerate the savings that could be achieved and so it denied a breach of Clause 7.2.

PANEL RULING

The Panel noted that by accessing the savings calculator readers could calculate how much they would save if they switched 100% of their prescriptions from brand leaders to the equivalent Galen branded generic medicines. The Panel noted that users had to input their annual average use of the brand leader in order to calculate the average annual saving. Assumptions and calculations were clearly stated. The Panel considered that although a 100% switch was unlikely, and the target audience would understand that to be so, it would nonetheless be seen as a goal in order to maximise any savings. In that regard the Panel considered that it would be impossible to design a tool which would, with complete accuracy, predict the percentage of prescriptions that would be switched and thus calculate the potential savings. The Panel considered that within the context of demonstrating to prescribers the potential magnitude of savings that could be made in one year by prescribing a specific Galen product instead of the market leader, the savings calculator was not misleading. No breach of Clause 7.2 was ruled.

B Trustsaver Collection Leavepiece

COMPLAINT

Norgine noted that the leavepiece featured the claim:

> 'With adopting Laxido Orange, Calceos and Flotros (trospium chloride) alone, an average-sized PCO (population~300,000) could potentially save per year:
>
> £270k'

Norgine noted that '£270k' was presented in much larger font size than the rest of the text of the leavepiece and was the dominant message. The assumptions and qualifications were in small font size at the foot of the piece.

In inter-company dialogue, Galen focussed on an assertion that as prescribers and budget managers were highly qualified and intelligent they would understand that any switch would not be instantaneous and savings would not be realised immediately. But it was in the presentation of these 'savings' that the problem arose in the leavepiece. In Norgine's view, stating £270k in such a prominent manner suggested little uncertainty in the figure. The claim was bold, with no qualification and so gave the clear message that if prescribers changed to the three Galen products this was what they would save.

To achieve these savings at a PCT level 100% of patients taking other products would have to switch to the corresponding Galen product overnight and all at the same time. In practice this would never happen. Norgine alleged that the claim was misleading in breach of Clause 7.2; it exaggerated the magnitude of savings achievable.

RESPONSE

Galen submitted that the leavepiece was withdrawn some months ago as a result of feedback from the salesforce that it had not had the desired impact with customers.

Galen noted that Norgine was concerned about the prominence of the £270K savings figure presented in the leavepiece and claimed that no qualification was given and that there was a clear indication that this was what prescribers would save.

The actual claim on the leavepiece regarding this figure read: 'With adopting Laxido Orange, Calceos and Flotros (trospium chloride) alone, an average-sized PCO (population ~300,000) could potentially save per year**'. This statement appeared directly above the quoted savings figure, in bold type and in a font size larger than a lot of the other text in the leavepiece. By using a savings figure based on an average-sized PCO, especially in such a clear and transparent manner, Galen had been mindful not to exaggerate the potential savings figure.

The caveat relating to this claim which appeared on the same page, also made it clear that the figure was based on a 100% conversion and that it was the maximum potential: '**This potential saving estimate is based on IMS data for an actual PCO with a population of approximately 300,000 and reflects the maximum potential based on 100% of prescriptions available being switched over to the applicable Galen product(s). Savings based on three of the trustsaver products only and on current list prices'.

Also directly opposite the quoted savings figure was a table which contained a final column entitled 'Potential savings against current market-leading brands'. The percentage cost savings figure for each Trustsaver brand against the applicable market leader was displayed. These figures were referenced to MIMS, Chemist & Druggist, IMS Data and data on file that demonstrated how the potential savings figures were calculated.

Galen repeated that it had not tried to portray that a 100% conversion would definitely occur or that any conversion would happen instantaneously. Also prescribers would know what approximate percentage conversion they were likely to realise locally and that any conversion would happen over a period of time.

Galen noted that Norgine raised various issues with the leavepiece in the first round of inter-company dialogue. However following Galen's response, there was no reference made again to a number of these in the second letter that Galen received from Norgine. Galen believed that some of these issues had been resolved following its response.

Galen denied that the leavepiece exaggerated the magnitude of savings achievable and thus denied a breach of Clause 7.2.

PANEL RULING

The Panel noted that the leavepiece was entitled 'Master the art of saving'. The headline across the inside double page spread was 'A smart choice for saving your NHS budget'. Readers were informed that the Galen Trustsaver collection of six branded generics offered significant savings against current market-leading brands. The claim at issue referred to three Galen medicines (Laxido Orange, Calceos and Flotros) and stated that the average-sized primary care organisation could potentially save £270k per year by adopting these medicines. Readers were invited to visit the Trustsaver website to calculate potential savings locally. The Panel again noted the assumption and calculations involved and the limitations thereof together with its comments at Points A1 and A2 above and considered that in the context of informing prescribers about the potential magnitude of savings that could be made in one year, the leavepiece was not misleading. No breach of Clause 7.2 was ruled.

C Trustsaver journal advertisements

COMPLAINT

Norgine submitted that the advertisements at issue came to its attention after it had concluded inter-company dialogue with Galen, but as the concerns it had were the same as it had with the items brought up in inter-company dialogue it included it in its complaint.

Norgine noted that the advertisements contained the claim:

> 'It may look like only a few pounds saved but to the NHS it could mean £45 million.'

As with practice level savings and PCT/CCG level savings this national figure for savings was completely unobtainable and was highly misleading for the reasons stated in points A and B above. There was no way in reality that 100% of NHS prescribers would switch 100% of patients to Galen medicines on day one and continue that prescribing pattern for 12 months. Norgine considered that the claim therefore greatly exaggerated the savings that might be made across the NHS if the Galen medicines were to be more widely used. A breach of Clause 7.2 was alleged.

Norgine stated that there were numerous reasons why an immediate 100% switch was an invalid assumption as mentioned above. Indeed some of these were reported in a PCT case study sponsored by Galen and available on the Trustsaver website. The article stated that 'The switch to Laxido from Movicol was introduced in April 2010, and by January 2011 (latest prescribing data available) 60% of prescriptions for Movicol/Laxido were prescribed as Laxido Orange', ie on the evidence presented, even with intense medicines management after 10 months there is only a 60% penetration rate for Laxido Orange. One of the reasons given for this was that there was some resistance from a small number of patients who did not like the flavour of Laxido - these patients were switched back to their preferred product by their GP. Other reasons could include time for change management, GP patient assessment and patient permission.

This PCT case study therefore showed that even with considerable work from the Medicines Management team and the local doctors, 100% switching was not possible, which undermined the fundamental assumption underlying the savings claims in the whole of the Trustsaver campaign.

Norgine submitted that it was important to appreciate that in any analysis of possible cost saving resulting from changing from one medicine to another, it was over simplistic to consider only the acquisition costs of the medicines as there might also be considerable resource and therefore additional cost implications (as was seen from the PCT case study). When conducting a cost-minimization analysis, all costs (resource expenditures) inherent to the delivery of the therapeutic intervention and that were relevant to the economic assessment should be measured. The Trustsaver campaign did not do this.

Any budget impact/cost tool must include at a minimum the core costs associated with the intervention ie costs associated with implementing change and all relevant comparators (Mauskopf *et al*). Its omission in not including fundamental basic cost components was misleading as it did not include all costs which might be involved when one product was switched to another.

A good example of the additional costs which should be considered was perfectly illustrated in the PCT case study on the Trustsaver website. The authors explained how the switch was managed:

'The introduction of Laxido Orange as an alternative drug was accompanied by written information – a detail aid – developed by the medicines management team to support all prescribers, including GPs and pharmacists.

In general:

- The medicines management pharmacist or technician identified the patients who were using Movicol.
- These patients were reviewed by their GP or practice staff, and the change to Laxido by prescribers was discussed.
- Formularies were changed on the computer system to remind patients about using Laxido Orange.
- ScriptSwitch and similar tools were used at the point of prescribing.
- When a switch was agreed, letters were sent to all patients to explain the change to their prescription.'

Therefore it was quite clear from this case study that the exercise was not instantaneous; it took some time with a considerable amount of effort required to implement this switch, all of which entailed costs (eg doctor's time, pharmacist's time, letters sent, updating IT systems).

Norgine thus considered that by just taking medicine costs into account and nothing else, and assuming 100% switch, Galen's claims greatly exaggerated the amount that might be saved in practice. Norgine alleged that the simplistic way the savings were calculated was misleading in breach of Clause 7.2.

RESPONSE

Galen submitted that the advertisements at issue had only recently been published (Date of Preparation: February 2012). Norgine had conceded that the issues that it had with these advertisements were never raised during inter-company dialogue.

Galen stated that the advertisements were part of an updated Trustsaver campaign. Although all of Galen's previous claims had complied with the Code, it reviewed these as part of the campaign update, and concluded that basing the savings claim on the current UK population was a better simplification. By using this methodology there was even less chance that a reader could misinterpret the claim. It was totally clear, open and transparent.

Galen noted that the savings figures presented in the advertisements were based on just three Trustsaver products; the potential savings figure available to the NHS based on the whole portfolio was considerably more than the £45M cited.

Galen reiterated that it was valid to base a potential savings claim on a 100% conversion. The footnote that accompanied a related claim in the advertisement read: 'This potential saving estimate was based on IMS data and reflects the maximum potential based on 100% of prescriptions available being switched over to the applicable Galen product(s). Savings based on three of the Trustsaver products only and on current list prices'. This footnote appeared in the same area of the advertisements as the potential savings claims. The reader could be in no doubt as to what the potential savings claims were based on.

Galen denied that the advertisements exaggerated the potential savings that could be made across the NHS and it thus denied a breach of Clause 7.2.

Galen noted that Norgine had cited a PCT case study that appeared on the Trustsaver website as proof that a 100% conversion was not achievable or realistic. This case study gave a real life example of a conversion from Movicol to Laxido Orange in which the actual degree of conversion was less than the potential. Rather than proving that a 100% conversion was not possible, the inclusion of this real life case study on the website illustrated that varying degrees of conversion were possible and showed that Galen had not been misleading; the inclusion of the case study showed complete transparency.

In addition, this was only one example from one particular PCT. As previously mentioned, Galen had data on file to demonstrate that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas. As previously stated this could be shared with the Panel if requested. Therefore presenting potential savings based on a 100% conversion was entirely valid.

Galen noted Norgine's submission that it was over simplistic to consider only the acquisition costs of the medicines and that when conducting a cost-minimisation analysis, all costs should be measured. However as previously explained, the potential savings claims used in the Trustsaver campaign were not part of a BIA or cost-minimisation analysis, they were part of a basic cost comparison that compared like-for-like products. An example was Laxido Orange, approved as a generic medicinal product of Movicol, yet 20% less expensive in both 20 and 30 pack sizes. As for the realisation that a conversion would not happen overnight, budget managers and medicines management teams were all highly qualified, intelligent and experienced, and would understand that resources would have to be implemented to effect a conversion. Galen also acknowledged that this would be the case. However in all of the Trustsaver materials it was made clear that the potential savings figures presented were based on medicine acquisition cost. It would be clear to health professionals that this was the case and that they would have to take account of any resources they would use in implementing a conversion. Again all calculations were accurate, open and transparent. Even after any conversion had been implemented (including any associated short-term resource costs), the savings figures were based on what would be spent on Trustsaver products vs the market-leading brands over a 12 month period.

Galen submitted that the way in which the potential savings were calculated was not misleading and so not in breach of Clause 7.2.

PANEL RULING

The Panel noted that the advertisements had not been discussed during inter-company dialogue. Nonetheless the issues raised by Norgine were so closely similar to those raised in relation to the Trustsaver website and the leavepiece, that the Panel considered that the complaint could proceed.

The advertisements showed two people in what appeared to be an art gallery. Three 'paintings' were packshots of Laxido Orange, Calceos and Flotros. In the middle of the 'gallery' there was a bigger-than-life-size pile of pound coins which one of the people was studying. The headline read 'It may look like only a few pounds saved but to the NHS it could mean £45 million'. The advertisement explained that Galen medicines offered significant savings against the current market-leading brands. The calculations and assumptions for the claimed savings were stated and as before they relied upon a 100% switch to relevant Galen medicines. As above the Panel noted the limitation of the assumptions together with its comments at Point A1 and A2 above and considered that in the context of informing prescribers about the potential magnitude of savings that could be made, the advertisements would not mislead the target audience. No breach of Clause 7.2 was ruled.

D Trustsaver campaign overall

COMPLAINT

Norgine submitted that it would be no defence of its complaints for Galen to assert that a lower standard was acceptable for health economic evaluations which were used for commercial promotion rather than for health economic evaluations used for other purposes. As noted in the Code, care must be taken that any claim involving the economic evaluation of a medicine was borne out by the data available and did not exaggerate its significance, and any assumptions made must be clinically appropriate, which clearly they were not in this case as 100% switching would never be achieved in practice.

Norgine considered the whole of Galen's BIA campaign was seriously flawed. It was out of line with guidance and good practice as to how such analyses should be conducted and presented. It singularly failed to maintain high standards in the area of economic evaluation of medicines. Therefore Norgine believed that the campaign as a whole warranted consideration of a breach of Clause 9.1.

Galen should have been aware of the misleading nature of the Trustsaver promotion, as it had the Galen sponsored PCT case study posted on the Trustsaver website. The case study showed that even with an intensive (and costly) medicines management programme, the PCT in question was only able to switch 60% of patients on Movicol to Laxido Orange over a ten month period. The continued use of claims of savings that Galen should have known was exaggerated and completely unachievable in practice, warranted consideration of a breach of Clause 2.

RESPONSE

Galen noted Norgine's submission that the significance of Galen's health economic evaluation was exaggerated and that the assumptions were not clinically appropriate as '100% switching would never be achieved in practice'. However as previously stated, the potential cost savings claims were not part of a health economic evaluation, they were part of a cost comparison. Galen had data on file to demonstrate that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas. This could be shared with the Panel if requested. Galen also knew that a 100% conversion had been realised for other medicines in various areas. Galen noted Norgine's allegation that the BIA campaign was seriously flawed and out of line with guidance and good practice and failed to maintain high standards in the area of economic evaluation of medicines. Norgine had therefore alleged that the campaign was a breach of Clause 9.1.

Galen fully understood and appreciated the special nature of medicines and the professional audience to which material was directed. While Galen was not an ABPI member company (like Norgine), its systems and procedures were written to be fully Code-compliant. The company was fully committed to adhering to the Code and regularly updated materials so that potential savings claims remained up-to-date and accurate. The basis of all calculations was made very clear to the audience and the professional nature of that audience was acknowledged in that it could interpret what degree of saving it was likely to achieve in its own particular area.

The Trustsaver campaign was a high standard, quality campaign and had been well maintained and constantly updated. Galen denied a breach of Clause 9.1.

Galen noted that Norgine had concluded by alleging that Galen should have known that the Trustsaver campaign was misleading and that continued use of exaggerated savings claims which were 'completely unachievable in practice' warranted consideration of a breach of Clause 2.

Galen took the allegation of a breach of Clause 2 particularly seriously as was demanded by the nature of the clause. Norgine had again referred to the PCT case study as a basis for citing a breach of this clause. As previously stated, this case study gave a real life example of a conversion from Laxido Orange to Movicol in which the actual degree of conversion was less than the potential. The inclusion of this real life case study on the Trustsaver website illustrated that Galen had not been misleading. In commissioning this article, Galen accepted that any degree of conversion could potentially be presented along with the fact that the article might include negative as well as positive feedback on Galen Trustsaver medicines. This was demonstrated by the inclusion of reasons why there was some resistance to a conversion from Movicol to Laxido Orange, such as patients not liking the flavour of Laxido. Therefore the article was entirely balanced and did not exaggerate the degree of a conversion that was possible in practice.

However, as previously explained, this was only one example from one particular PCT and data on file demonstrated that a 90%+ conversion had occurred from Movicol to Laxido Orange in practice in some areas. Therefore presenting potential savings based on a 100% conversion was entirely valid. Galen had data on file to demonstrate that a much higher degree of conversion actually had been achieved in practice and that a 100% conversion was indeed possible. This data could be shared with the Panel if requested.

Galen submitted that rather than bring discredit upon, and reduce confidence in, the industry, the Trustsaver campaign had demonstrated how a pharmaceutical company could work with the NHS in order to bring about a cost benefit to the health service whilst maintaining patient care. A measure of how well the campaign had been accepted by health professionals was demonstrated by the degree of adoption across the UK of products from the Trustsaver portfolio, and the fact that Galen had not received a single complaint from a health professional in the two years that the campaign had run.

Therefore Galen totally refuted the alleged breach of Clause 2 and considered that this was a malicious attempt by Norgine to discredit an effective and compliant campaign.

PANEL RULING

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

The Panel did not consider that the Trustsaver campaign was such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

Complaint received **23 March 2012**

Case completed **29 June 2012**