

Spurious Claims for Health-care Products: An Experimental Approach to Evaluating Current UK Legislation and its Implementation

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Abstract: The lay media, and especially the Internet, contain many misleading claims for health products which have previously been inadequately regulated by consumer law. This was an experimental interventional survey within a consumer health-care setting. Three health products were chosen on the basis of being widely available on the UK market and having no available evidence of effectiveness. Twelve volunteers submitted 39 complaints to Consumer Direct (UK portal for the regulator Trading Standards) regarding false health claims, and 36 complaints were followed up for a maximum of 4.8 months. The mean time from submission of complaints to Consumer Direct to acknowledgement by the relevant Trading Standards office was 13 days. There were no responses from Trading Standards for 22% of complaints. At the end of the study one supplier had amended their website following Trading Standards advice, but did not stop all health claims. Another stopped advertising their product on the Internet and the third continued the health claims unchanged. EU directive 2005/29/EC is largely ineffective in preventing misleading health claims for consumer products in the UK.

Introduction

Many consumers are currently misled by unsubstantiated therapeutic claims. This puts people at risk of using ineffective treatments or wasting money.¹ The Consumer Protection from Unfair Trading Regulations 2008 (CPRs)² is the UK implementation of EU Directive 2005/29/EC, the Unfair Commercial Practices Directive.³ Among a wide range of practices that are considered by the CPRs to be unfair, is “Falsely claiming that a product is able to cure illnesses, dysfunction or malformations” (Clause 17). The CPRs require the trader to back-up their claim with evidence.

The authority responsible for enforcing this new consumer legislation is Trading Standards (TS). Local TS offices are operated by local government, but are accessed by the public via a centralised gateway, Consumer Direct (CD), an organisation which deals with the full range of consumer legislation, and gives advice to consumers. This gateway was set up at approximately the same time as the CPRs came into force, but is not linked to the CPRs.

The aim of this study was to test the implementation of “The EU Unfair Commercial Practices Directive” in the UK through “The Consumer

Protection from Unfair Trading Regulations 2008”, with regard to health claims made by suppliers of consumer products.

Methods

Three health-care products were selected from the UK market (see Table 1). The selection criteria were:

- Widely marketed within the UK, such as on a trader’s website, in a national retail chain, and/or advertised in the national press or broadcast media;
- No reliable evidence to support the claims made by the retailer and/or the manufacturer. Evidence was sourced from *The Desktop Guide to Complementary and Alternative Medicine*,⁴ and backed by literature searches in MEDLINE, EMBASE, CINAHL, AMED, PsycINFO (from their inception until 31 July 2010), using keywords, product name, active ingredient names, disease or condition;
- Any disagreements between authors (LR, PP, EE) regarding the selection criteria of products were resolved through discussion. Each of these investigators handled all three products selected.

Fifteen volunteers agreed to take part in the experimental testing. Four were members of HealthWatch UK, and others were independent people with an interest in health care.

Investigators asked traders via email for clinical trial evidence to support their claims advertised, for each of the three selected products. Investigators explained that the enquiry was for research purposes, and that a reply within one week was required. Therefore each trader was to receive 15 enquiries from the group of investigators. Two investigators withdrew at the start of the study, leaving 13 who contacted traders. One investigator withdrew later and did not follow-up complaints.

All replies from traders were collated in a central database and independently verified by LR and PP. Only randomised controlled trials (RCTs) published in peer reviewed journals were considered valid sources of evidence to support their claims; consumer testimonials were not accepted. For claims verified as false, or if traders failed to reply on time, investigators made complaints to CD, stating why they believed the claim was false. Complaints were made via the CD website.⁵

The study was conceived by HealthWatch (registered charity number 10093992). The protocol was approved by the HealthWatch committee. No patients

Table 1 *Health claims selected and responses from traders to requests for evidence*

Trader/Product	Claim(s) (quote)	Comment	Number of responses from traders	Summary of responses
Boots/Boots Detox 5 Day Plan Strawberry Flavour	“help flush away toxins and stimulate your body’s natural detoxifying systems leaving you purified (sic) and revitalised (sic)”	Available online and in retail shops	10	The trader failed to supply any evidence and suggested that The European Food Safety Authority is responsible for verifying health claims
World Wide Shopping Mall/Health Aid Shark Cartilage	“Boost the immune system Reduce inflammation Act as a pain reliever Help with the symptoms of inflamed joints and cartilage Protect the body against harmful diseases”	Only available online	10	The trader replied saying that no evidence was available, and referred further enquiries to manufacturer
Bohemia Style/Easy Diet Red Seaweed Dietary Supplement	“Red Seaweed helps reduce your risk of breast cancer Helps lower hypertension Prevents hypothyroidism”	Only available online	0	12 investigators tried to fill in online form, with no confirmation of receipt; tried email, and got delivery status notification, failure; could not find address on website

participated in this study; therefore, no ethical or regulatory approval was required.

Results

Details of the health claims selected and the responses received from the three traders are presented in Table 1.

Bohemia Style did not respond to any requests, whether by email or telephone. It became clear that this was a misleading website, publishing a UK street address that the trader had not actually used, and that the trader was operating from the USA. TS officers did not think that it would be possible to take any action against an overseas trader, although the matter remains open at the time of writing.

Boots responded by sending the same statement to all investigators. The 328 word statement did not address the matter of evidence. World Wide Shopping Mall attempted to avoid responsibility for their shark cartilage claims, stating that these came from their supplier Health Aid. Some investigators became involved in quite protracted exchanges with World Wide Shopping Mall, who appeared to be motivated to understand why they were being asked for evidence. The mean time from submission of the complaint via the CD website to response from TS was 13 days. However this does not represent substantive responses, but simple acknowledgements. No replies at all were received from TS to eight complaints (22%).

Follow-up contacts by investigators were mainly via email, but telephone contacts were also tracked. In addition, there were 15 substantive contacts from TS officers. Some of these covered more than one complaint, and some were directly in response to investigators pressing for information. Overall, the first complaints were submitted on 7 September 2010 and the last on 11 October 2010. Follow-up began on 9 September 2010, and no further contacts were made after 31 January 2010, the planned end of study. Each product received a total of 58 follow-up contacts, because each investigator followed up all three product complaints within the one email or telephone call.

Initial dialogues with TS officers revealed that one trader, Boots, had a “home authority” agreement with TS. The normal process is that a complaint is directed to the TS office of the local authority in whose area the trader is situated. In the case of traders with multiple outlets, they can elect to nominate one TS office

to deal with all outlets. In the case of Boots, the nominated office was Nottingham. Most investigators were told by TS officers that the matter had been referred to the Nottingham TS office, which stated that a meeting was held with Boots on 15 October 2010 to discuss the claims for the 5-Day Detox product. The TS officer stated that the outcome of this meeting would be reported back to the investigators concerned (several received the same message), but nothing further was heard.

All investigators specifically cited the CPRs when making complaints. TS officers consistently responded to investigators by refusing to consider the CPRs, and instead referred to the Food Standards Regulations. These they defined as “primary legislation”.

At the end of the study on 31 January 2011, the Boots website had not been changed. The World Wide Shopping Mall claims for the shark cartilage product had been reduced to “supporting the immune system”, which most TS officers considered to be a satisfactory outcome. The page for the Bohemia Style seaweed product was deleted from the website but the traders issued no statement about this.

At the end of the study, no TS officer had responded to any investigators with an outcome of their discussions with Boots. One investigator received a letter from Buckinghamshire TS dated 4 April 2011, stating that the Boots website text had been changed to “Boots Detox 5 Day plan is an apple flavoured vitamin and mineral food supplement”. Subsequently the whole range of 5-day detox products disappeared from the website, and was discontinued from sale in retail stores. However, we learned that several complaints had been independently submitted to the Advertising Standards Authority (ASA), so this outcome may be unconnected with our study. To illustrate the inconsistent and unclear treatment of the complaints, Table 2 shows a selection of statements from TS officers.

No prosecutions were brought under the CPRs for false health claims as a result of our complaints.

Discussion

The aim of this study was to test the effectiveness of the Consumer Protection from Unfair Trading

Table 2 *Trading Standards' statements on products and complaints*

Product	Statements
Boots Detox 5 Day Plan	<ol style="list-style-type: none"> (1) Referred to Home Authority TS for Health Aid awaiting EFSA publication of completed list (2) TSO was insisting on food registrations. (3) Local office does not appear to know how to respond to referrals from TSO except when claim refers to local business issue. Referred all other issues back to TSO (4) "The website's domain registrant is located in Florida. We can therefore take no further action in respect of this matter" (5) Since Boots are based in Nottingham, the complaint will be forwarded to the local TSO for action if any
Health Aid Shark Cartilage	<ol style="list-style-type: none"> (1) Referred to Home Authority TS for Health Aid awaiting EFSA publication of completed list (2) TSO was insisting on food registrations (3) Home Authority TS advised they have passed on details to manufacturer's TS office. (4) Since this trader is based in North Yorkshire, the complaint will be forwarded to the local TSO for action if any (5) Initial promise to look into complaint lodged with TSO, no further response
Easy Diet Red Seaweed	<ol style="list-style-type: none"> (1) The TSO legislation only covers the UK (2) TSO will inform the MHRA who may put a warning about this company on their website if they think it appropriate (3) TSO also said that legislation in the USA is much laxer than the UK and this trader could well be operating legally (4) TSO will contact the Food & Drugs regulatory body in the USA to inform them of the website (5) TSO referred to Advertising Standards Authority (6) Referred to Office of Fair Trading (7) Outside UK's jurisdiction (8) TSO is unable to identify UK address of Bohemia Style, hence no action can be taken (9) Claim passed to FSA. Claim DoH's responsibility (10) "Your queries have been passed to the Home Authorities concerned. This is the end of the matter as far as we are concerned, as with Home Authority referrals it is then for those Authorities to approach the companies and deal with the concerns"

Regulations 2008 in the UK. Our results showed that the CPRs are largely ineffective in the case of false health-care claims for three health products. More importantly, however, we indicated that TS officers misinterpret currently available law by failing to prosecute traders for false health claims they make. This means that the UK government has failed to comply with the EU law under the Directive 2005/29/EC. As a result of our study, a formal complaint to the European Commission is justified.

The CPRs provide for a court to demand evidence from a trader, and if the evidence is not available, the claim is held to be unlawful: Section 17 of the CPRs clearly state that false claims to "cure illnesses, dysfunction or malformations" are always unlawful. In this study, we have also pointed out that traders frequently ignore the CPRs and continue to mislead the public with regard to its health.

TS officers use the concept of "primary legislation", meaning that which covers a particular type of product. The authors were unable to find any authoritative definition of the term. TS officers claim that primary legislation should be used instead of more general legislation, despite the fact that the primary legislation is quite often much less effective. Correspondence from one TS office agrees that the CPR official guidance from the OFT requires TS to enforce the CPRs, and that "all appropriate means" shall be used for this. The officer stated: "In my opinion, the 'most appropriate means' in this matter are the Nutrition and Health Claims Regulations 2007." This argument appears logically flawed, in that TS agrees that this legislation is unsatisfactory while claims are being evaluated by the European Food Safety Authority (EFSA). The EFSA is currently evaluating thousands of claims

for ingredients, and while a particular claim has yet to be evaluated, TS officers take the view that it cannot be challenged. The “means” therefore are neither effective nor appropriate. This is confusing and judicial review might be necessary to avoid a situation where something is legal under one law but illegal under another. It would also help to prove more effectively that an offence has been committed. TS argues that a claim must be allowed if it is considered legal under “primary legislation”. In the case of the nutrition-related regulations, considered primary by TS officers, the claims are not in reality legal, they are simply awaiting evaluation. A claim made by Boots for example should be considered invalid until it has supportive evidence. Clearly there is a mismatch between the logic underlying the evidence base, and the application of consumer law in terms of health-care products in this country.

It is likely to be several years before the majority of health claims have been evaluated by the EFSA, reported to the European Commission and voted into law. Meanwhile false claims by traders are not regulated, if the product is deemed by TS to be a food or a supplement. Yet the CPRs effectively outlaw all false claims by traders, and place the burden of proof on the trader and not on the customer. We found that TS officers did not appreciate this difference, and continued to argue that they would have to engage expensive expert witnesses to prove a claim wrong.

Although not strictly within the scope of the protocol, after the end of the study Boots decided to drop the claims and eventually to discontinue the product from sale, possibly because of the volume of requests for evidence, or after discussions with the TS home authority. Seven months elapsed between submission of the first complaint to CD and removal of the claims. It is impossible to ascertain how this came about because TS officers have not reported their discussions with Boots. For all this time, Boots may have continued to profit from the sale of the product and consumers were exposed to false claims and financial losses. We consider that far more timely action by the regulators would be appropriate. Currently TS does not take any initiative with regard to such false claims, and it is left to private citizens to submit complaints in order for any regulatory action to take place.

The Office of Fair Trading has announced a new development which may improve the

enforcement of the CPRs.⁶ A pilot scheme, involving fixed penalties as an alternative to prosecution, is now in progress. However, the scheme does not address the reluctance of TS officers to apply the CPRs at all.

This appears to be the first formal study which has tested the CPRs. Whereas there are anecdotal reports suggesting that consumer protection law is inadequately enforced, in this study we attempted to measure the level of enforcement quantitatively. We aimed to derive descriptive statistics on the number of complaints satisfactorily resolved, and the time from submission of the complaint to a satisfactory outcome.

There were several limitations of this study: the number of products and complaints is limited; the moderately high dropout rate (20% of investigators who withdrew) might have affected our findings; it was not possible to test the effectiveness of the CPRs, because they were not being applied by TS officers. All investigators were obliged to liaise directly with their local TS offices, who were dependent on the “home authorities” for taking any action. Therefore, it was difficult to obtain adequate information on the progress of complaints. We could not be certain that the outcomes reported here were unconnected with any other activities, for example complaints submitted by other parties or to other regulators. Therefore our conclusions must be conservative.

As consumer protection law for health-care products is largely ineffective, clinicians are likely to encounter increasing numbers of patients who have been put at risk by relying on false claims for these products. It is well recognised that serious harm can be caused.⁴ The effect of this would be to increase the burden of untreated disease which has been allowed to progress, placing further demands on health-care resources, mostly in primary care.

This innovative exploratory study found an unexpected reluctance of TS to implement the CPRs.⁷ We recommend that further studies should be carried out on health-care claims for products which cannot be considered foods or food supplements. A larger study or audit is needed to show the extent of European law being implemented in the UK. As enforcement might not always necessitate prosecution, an outcome measure for such a study could be the proportion of traders who stopped

making false claims when advised to do so. However, from what has been observed in this study, follow-up would have to be longer.

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