

HealthWatch

for science and integrity in health care

Research Report

Testing the Effectiveness of Consumer Legislation for Health-Related Claims

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1 Synopsis

1.1 Background and Rationale

Many websites make health-related claims without providing robust evidence. As well as breaching advertising standards, these traders also violate consumer legislation. A previous pilot study¹ found that enforcement of consumer legislation with regard to misleading health claims was largely ineffectual. This study was designed to focus on the Consumer Protection from Unfair Trading Regulations 2008, and to assess a wider range of marketing claims.

1.2 Study Design and Conduct

Ten websites were selected, that were making health-related claims which lacked supporting evidence. These included homeopathy, crystal healing, electronic diagnostic devices, copper bracelets, colonic hydrotherapy, static magnets, far infra red therapy, and massage cups.

Thirteen volunteers were each allocated up to five health claims to challenge (of the 10 selected). Hence each trader received several challenges, ranging from five to 12. Volunteers asked traders to provide evidence for their claims. None did, but three removed their claims from their websites. Volunteers then sent the remaining traders a 'cease and desist' letter, warning them that failing to comply would trigger a complaint to the authorities. One further trader removed claims at this stage.

1.3 Main Outcomes

A total of 38 complaints were submitted to Trading Standards (TS), via the Citizens Advice website. We identified 13 local TS offices to whom Citizens Advice forwarded complaints. Only 18 complaints (64%, of known data) drew a response from TS offices. Of these, response times ranged from 10 to 74 working days (median 31).

Complaints were followed up by volunteers for six months. Two traders received advice from TS, and removed their claims. Two traders were referred to the MHRA (who took no action). In total, only four enforcement actions by TS could be identified, although two complaints were unresolved after six months.

There was wide variation between TS regions as to their responses. For example Merton TS did not consider that the copper bracelets trader was in breach of consumer law, while Wiltshire TS did – but still refused to take action.

1.4 Conclusions

Our volunteers found that making and tracking complaints to TS was extremely cumbersome. Thus 74 requests were made to traders for evidence, but only 38 complaints were made to TS. The study suffered from a large volume of missing data for this reason, but the lack of TS action can be verified by most websites subject to complaints, continuing to make unwarranted claims. In several cases TS offices referred complaints to another region, from whom nothing was heard.

2 Study Team

Project Manager	Les Rose			
Assistant Project Manager	Roger Fisken			
Investigators	Colin Brewer Lynette Fox Marie Jasim George Gillett Roger Fisken Kathryn Rothwell Rebecca Dewey Sofia Hart Charlotte Rose Justin Seabrook Susan Bewley Adam Jacobs Debra Bick			
Data Analyst	Professor John Kirwan			

3 Approvals

This report was reviewed and approved by the HealthWatch research subcommittee.

Date of approval:

31-3-2017

Signed

James May

HealthWatch Chairperson

4 Introduction and Rationale

4.1 Previous Research

A pilot study was carried out by HealthWatch and published in 2012¹, which showed that the Consumer Protection from Unfair Trading Regulations 2008 (the CPRs)² were not being enforced by Trading Standards (TS). There were several reasons for this:

1. The CPRs were not applied when TS considered that other legislation was available. In most cases food regulations were applied (if any action at all was taken).
2. TS argued that false health claims were not a high priority, and that resources had to be directed to other more common breaches, such as financial fraud.
3. In nearly a quarter of cases Trading Standards Offices (TSOs) failed to respond at all.

A key issue was that, even when TSOs did respond, they took many months to engage with the traders making the claims, during which it was business as usual for the traders. For some complaints TSOs, even after acknowledging the complaint, failed to report any outcomes at all.

4.2 Legal Advice

HealthWatch commissioned advice from a law firm specialising in consumer affairs. This advice is to be found in section 18.3 on page 34. A key finding is that the CPRs are regarded as 'gap-filling' legislation, to be used when other product-specific legislation does not exist. In this respect TSOs were technically correct to apply (for example) food regulations in the pilot study, as some of the products could be classed as nutritional supplements. Also, at the time of the study, the European Food Safety Authority (EFSA) was finalising the list of permitted nutritional claims for foods and supplements. The EFSA list is curiously incomplete in some ways, with some established uses such as vitamin D for bone health not being approved. This is because EFSA only approves claims that manufacturers have submitted. Trading Standards has taken the view that, until EFSA has actually refused a claim, traders are permitted to make it.

The advice also highlighted the nature of the claims with regard to the target consumer. If claims are medicinal, ie aimed at specific medical conditions, then The Medicines Act 1968 applies, and the regulator is the Medicines and Healthcare products Regulatory Agency (MHRA). It is not the purpose of the present study to test enforcement by the MHRA. The scope of this study is health claims directed towards the 'worried well', ie people with no actual clinical indications but wishing to improve their health generally.

However this does not mean that misleading claims falling within the scope of consumer legislation are necessarily benign. People may seek remedies for minor complaints that could signal more serious medical conditions, so the selection of products for this study needed to be precise. This is because a criterion for TS to take action is the vulnerability of the consumer, alongside a significant risk to public health.

HealthWatch volunteers would not necessarily be regarded by TS as 'average consumers', but complaints would need to be worded so as to clarify that an average consumer would be unfairly influenced.

TS referred previously to other 'established means' of obtaining compliance with legislation, one of these being the Advertising Standards Authority (ASA). This is discussed in the next section.

The lawyers advised that complaints to TS should be fully documented. In particular, considerable

weight would be added by sending the trader a 'cease and desist' letter. This is because a provision of the legislation is to prioritise persistent offenders. Ignoring a warning to desist would be considered persistent. All of this means a significant increase in the workload required to submit a complaint.

In response to this advice, we asked in what circumstances the CPRs Schedule 1 Para 17 prohibition of falsely claiming to cure any disease etc could ever apply, if such claims would normally be considered medicinal and fall under The Medicines Act. Further advice was thus received, and this has been added in section 18.3.2 on page 41. The conclusion is that TS has considerable discretion as to which legislation to apply, as many relevant products are considered 'borderline'. Therefore a useful outcome to assess in this study is whether TS referred complaints to the MHRA, whether the latter took any action, and whether TS followed up with the MHRA to verify the outcome.

We also received separate legal advice on a previous occasion. This made two important points:

1. TS has commonly argued that they carry the burden to prove a claim is misleading, and that they do not have the resources to do that (eg by engaging expert witnesses). This is not strictly true. For ordinary commercial claims, such as the volume of beer served in a bar, the burden does rest on TS. However claiming that (for example) a crystal vibrates with invisible energy and can treat various medical conditions, is an extraordinary claim because it has no scientific basis. This shifts the burden of proof to the person making the claim.
2. TS has also argued that for a health related claim, the trader must use the word 'cure' to be in breach of the CPRs (see Schedule 1 para 17). This however is not the only relevant clause. For example a misleading claim is also caught by Regulation 3(3) and by Regulation 5. In other words, the CPRs have a wide range of provisions for identifying misleading claims, and TS is wrong to dismiss a complaint because one particular clause does not cover it.

4.3 Other Regulation

There is a great deal of experience among health-related sceptics of submitting complaints to the ASA, which usually operates with rigour and efficiency. It is however a voluntary code, and whereas many advertisers do comply with ASA advice and adjudications, some do not and are placed on the ASA's non-compliance list. TS has now taken the role of back-up authority for the ASA, which can refer persistent non-compliers for TS action. Only very few cases have got this far hitherto, and have taken many months in every case. For this study, ASA referral was avoided, as the objective was to assess TS effectiveness. Hence, more serious breaches were prioritised, as less serious ones (as perceived by TS) could be diverted to the ASA as 'established means' of enforcement.

5 Study Objectives

To assess the effectiveness of UK consumer legislation in regulating commercial claims related to health benefits. This was categorised as follows:

- The extent to which established legislation is enforced by Trading Standards
- The extent to which newer legislation is enforced, specifically the Consumer Protection from Unfair Trading Regulations 2008 (the CPRs)
- The overall distribution of enforcement among the various types of legislation available to Trading Standards.

6 Study Design

The study flow chart is shown in section 18.1, page 28.

6.1 Selection of Claims

- The protocol specified that at least 20 volunteers would be recruited from HealthWatch members and other groups or individuals.
- Volunteers (hereafter termed 'investigators') were to nominate to the project manager any products which they considered to be making clearly misleading health claims. These were to be fairly widely marketed nationally, with a potentially large target population. Criteria were:
 - Non-medicinal claims only.
 - Not interpretable as food-related products.
 - No published robust peer reviewed evidence supporting the claims.
 - Services could also be nominated.
 - Promoted via websites.
- A sample size calculation was not feasible, but it was decided to specify a number of product claims representative of the whole range of claims on the market. A minimum of 10 claims was expected to be a fair sample of the market, with regard to the practicalities of running the study.
- Candidate products were nominated to the project manager by the investigators. The 10 products most frequently nominated by the investigators were selected.
- The project management team carried out literature searches for evidence supporting the claims nominated. If any robust evidence was found, the product was to be withdrawn from the investigation and replaced.
- If there was any doubt as to the applicability of the CPRs, the project manager was to refer the product to the legal advisers, who would advise on the legislation most likely to be used by TS.

6.2 Submission of Complaints

As TSOs tend to dismiss isolated complaints, each claim had to be subject to several complaints. Each investigator was to submit complaints on five products. The allocation of products to investigators was randomised. Hence, each product would generate 10 complaints. The process was as follows:

1. Each investigator received a list of claims, which had been through the process in 6.1 above.
2. Investigator emailed trader and asked for evidence. Investigators explained that the enquiry was for research purposes, and that a reply within one week was required.
3. Unless previously unknown evidence was provided by the trader, the investigator sent the trader a 'cease and desist' letter (see Appendix 2 section 18.4 for the template).
4. Once claims had been verified as false, or traders had failed to reply on time, investigators made a complaint to the Citizens Advice website, stating why they believed the claim to be false.
5. Investigators prepared supportive information, including a detailed letter to Citizens Advice/TS (depending on who responded), for which a template was provided (Appendix 3 section 18.5). There was no need to purchase the products concerned, but investigators needed to provide concrete evidence of the claims, for example screenshots of the relevant web pages.
6. All progress was logged on-line in the CPR2 website.

6.3 Follow-up of Complaints, and Assessment of Outcomes

Complaints were to be followed up at least monthly for a period of 26 weeks. The following assessments were to be made:

- Percentage of traders who responded to requests for evidence
- Percentage of traders who responded to 'cease and desist' letter, and removed claims
- Time from initial complaint to response from Trading Standards
- Percentage of complaints which resulted in enforcement action by TS within the follow-up period. Enforcement actions were categorised as follows;
 - Trader complied with TS advice to desist.
 - TS advised trader, but trader did not comply.
 - Case referred to another regulator.
 - TS prosecuted trader.
 - TS took no action.

7 Data Management

A web-based system of data capture forms was set up using Google Forms. Data entered were stored as Google Sheets, which served as the study database. Investigators entered the following information into the study website:

- Trader details - name, address, product or other commercial offer
- Details of claim and trader's web address
- Date claim was seen
- Date complaint submitted to Citizens Advice (CA)
- CA reference number
- TS office to which CA sent the complaint
- TS reference number if different
- Dates of all subsequent contacts with CA and TS, and summaries of discussions.

8 Data Analysis and Reporting

8.1 Data Analysis

Descriptive statistics only were presented. No analytical statistics were appropriate, as no groups were being compared. Data were exported to an offline application (Microsoft Excel version xxx) for analysis. Data were displayed as tabulations.

8.2 Reporting

The outcomes of complaints will be written up for publication in a peer reviewed journal. For this reason investigators have retained all communications, including emails and records of telephone calls, as source data. All investigators' contributions are to be acknowledged in the report.

9 Project Management

It was intended that the full set of complaints needed to be made within one month of the project start, to enable easier tracking by the project manager. Because of withdrawals by a large proportion of investigators, this objective was not met. Investigators had to be replaced frequently, rendering any formal project management impractical.

10 Project Sponsorship

This study was conceived among members of the charity HealthWatch. The study was supported by the HealthWatch Research Fund.

11 Project Governance

No health care consumers were involved in this study, so no ethics approval was required. The purpose of the study was to evaluate the activities of the statutory authorities in enforcing the law, and not to test any medical product. Therefore no regulatory approval was required.

The protocol was reviewed by the project team, and was approved by the HealthWatch committee.

The HealthWatch committee reviewed progress at scheduled committee meetings. This was documented in minutes of the meetings.

12 Study Quality Assurance

The project manager reviewed the raw data and checked for missing values. Where possible, missing data were recovered by querying investigators via email. All investigators were instructed to retain source data, which comprised email messages, letters, and telephone call records. In some cases these were used to complete missing data fields. It was not considered appropriate to carry out an audit of the study, as it was not expected that all records would be complete. This was because the availability of data depended on compliance by external parties, mainly Trading Standards.

13 Results

13.1 Study period

The first request for evidence for a health claim was made on 1st March 2015 and the last contact with Trading Standards was recorded on 2nd August 2016.

13.2 Study team

A total of 44 people volunteered to act as investigators. Only 13 of these entered data, and nine followed up complaints to study end. The first record was dated 3rd August 2015 and the last was on 8th September 2016.

13.3 Claims selected for assessment

Table 1 on page 20 lists the claims that were selected. As specified in the protocol, all claims were made in traders' own websites, and the URLs shown were correct at study start. As per the protocol, ten claims were selected.

13.4 Study disposition

After the study started, it became apparent that there could be variation between Trading Standards (TS) offices regarding responses to complaints. Hence the management team attempted to record the local authority areas in which they operated, as TS offices are operated by local government. Table 2 on page 22 lists these local authorities. These were recorded for all investigators who submitted complaints. All local authorities were in England, so we would expect some consistency in handling of complaints.

For the whole study, 79 requests for evidence were made to traders. There is considerable variation between regions in terms of study activity. This is partly explained by random effects; for example, by chance there were two investigators in each of the London Boroughs of Merton and Lambeth, and in Nottingham. Also for some claims activity had to be stopped because traders removed claims when challenged. This is explained in section 13.5 below.

13.5 Evidence, complaints, and follow-up

As noted above, 79 requests for evidence were made to traders (table 3, page 23). Two traders did not respond to any investigator, and responses to others were variable. It is likely that after more than one request some traders decided not to respond further. Overall 28% of requests elicited a response, with four traders sending what they claimed was evidence. In no case was this evidence adequate, ie it was not from high quality randomised controlled trials. Three traders quickly removed their claims from their websites.

All traders were therefore sent letters to cease and desist their misleading claims. It should be explained that investigators issued their requests for evidence over a period of nine months, so the situation was compromised by traders repeatedly removing and reinstating claims. The three which removed claims after requests for evidence, did so only after more than one request, so that some cease and desist letters were sent before the removals.

These letters were sent after 70% of the requests for evidence. The reason this is not 100% is because of issues with investigator compliance. In addition to the original three traders who

removed claims previously, Get FITT Ltd did so after a cease and desist letter. This trader had previously to this study been disciplined by the Advertising Standards Authority.

Thirty-eight complaints were submitted to Trading Standards (TS) via the Citizens Advice website (table 4, page 24). These were mostly acknowledged by Citizens Advice – 78%. It was decided not to continue the study for three traders, who removed claims early. Sixty-four percent of complaints to Citizens Advice were acknowledged by TS. This means that over one third were not acknowledged. If it did respond, Citizens Advice did so quickly, with a median of three working days, but TS took a median of 31 working days to respond, equivalent to six weeks. Note that missing data will have affected the percentages. Data analysis did not assume that a missing data point indicated a lack of response from either Citizens Advice or TS, so the analysis was conservative, in favour of both bodies. There were two missing data points for Citizens Advice and eight for TS.

Investigators were asked to follow up complaints with emails and telephone calls, and these data are shown in table 5 on page 25. This was not effective if TS did not respond initially, as investigators did not have contact details, and the latter were not passed on by Citizens Advice. Where contact details were known, letters were sent containing more detail than in the original complaint, and setting out key points as per the legal advice received (see section 18.5 on page 51 for the template). Forty-six follow-up letters were sent, regarding 38 complaints. In some cases contacts were repeated when TS asked for more information. There were 35 contacts from TS offices, and a further 43 contacts by investigators to TS offices. This shows that there was almost twice the number of contacts initiated by the study team, compared with responses from TS offices.

Outcomes of complaints are shown in table 6 on page 27, ordered by trader. The data are very incomplete because of lack of communication by TS offices. Two traders, The Crystal Healer and The Wellbeing Clinic, appear to have removed claims in response to TS advice. Asyra was referred by TS to the Medicines and Healthcare products Regulatory Agency (MHRA), and as documented in the HealthWatch newsletter³ no action was taken by the MHRA. TS also referred Christine Wilson (homeopath) to the MHRA, who declined to take action and referred the case back to TS. No further action was taken by either body. The study timed out before all outcomes could be captured; certainly for Halcyon Bracelets and Amazing Health no outcomes were known at the six months time point.

In table 7 on page 20 the outcomes are displayed according to TS office. Of 34 complaints which could be reliably assigned to a local authority, the largest number was sent to Nottingham (9). It was confirmed that this TS office advised traders to remove claims for two complaints, but took no action on four. It seems likely that the remaining three outcomes were unknown because they were also not actioned. The London Borough of Merton received eight complaints, and took no enforcement action according to information received. Of seven complaints received by the London Borough of Lambeth, action was only taken against one trader. Complaint numbers for other TS offices are too small for meaningful analysis, but overall of 34 complaints, enforcement action can only be identified for four of them.

13.6 Responses from Trading Standards

Some of the responses from TS officers illustrate their diverse approaches to complaints.

Halcyon Bracelets made the following claim:

“I have been a sufferer of Restless Legs at night for over 35 years. ...Halcyon bracelets contain 99.9% pure copper which has been used as a natural remedy for many ailments for centuries and they are nickel free, so they are perfectly natural. I have tried other types of copper bracelets over the years (when perhaps I've forgotten them when going away) but no others have ever suited me as

well as the ones I first came across all those years ago.”

To one investigator the TS office in the London Borough of Merton replied:

“Having considered this complaint I am of the opinion that the information provided on the website is simply experience of the seller. Seller has suffered with RLS for a long time and discovered that a particular bracelet containing a specific copper was providing tremendous relief. Seller modified the original bracelet and today sells a pair as Halcyon Bracelets. I do not consider the information to be an infringing CPRs (sic) and seller does not claim any defined cure or treatment benefits but remedy to sufferers based on her experience. She offers money back after 4 weeks use if the bracelets do not offer the buyer the same relief.”

However Wiltshire TS replied as follows regarding the same trader:

“www.asyra.co.uk and www.halcyonbracelets.com are both making specific claims about specific products. Trading Standards are not best placed to determine the accuracy or otherwise of these claims and have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed. We would need to prove that a claim is false or misleading beyond reasonable doubt before we could consider taking any formal action. However, the Advertising Standards Authority (ASA) now has marketing on companies’ own websites, as well as external advertising, within their remit. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. Consequently you may wish to refer your concerns about any specific claims on these websites to the ASA.”

In summary, Merton TS did not consider that a claim had been made, whereas Wiltshire TS did. But Wiltshire TS still refused to act against the trader. To a different investigator, Merton TS replied as follows:

“Thank you for your recent correspondence.

Please find a ruling by the Advertising Standards Authority with regard to the Halcyon Bracelets at https://www.asa.org.uk/Rulings/Adjudications/2015/2/Halcyon-Bracelets/SHP_ADJ_279436.aspx Essex Trading Standards are currently considering the matter in light of current advertising and ASA ruling.”

This ASA ruling (which is unrelated to the present study) is dated 18th February 2015, and the trader has been on the ASA’s non-compliers list since 4th January 2016. As of 17th December 2016 Halcyon Bracelets had still not been referred to Trading Standards, and the claims were still on the website. It is noteworthy that Merton TS gave different responses to different complainants, for the same complaint.

The Crystal Healer made the following claims:

“Red jasper helps to prevent illness, enhances psychic protection and is especially powerful against witch craft when combined with jet. Red jasper promotes re-birth, new ideas, astral travel, meditation, your basic survival instinct and dream recall. Perhaps red jasper's best attribute is as an all round tonic for the body helping to both heal and prevent minor illness such as colds and flu.”

Nottingham TS replied as follows:

“Each year this Service receives thousands of complaints and our most effective response is to prioritise those we directly investigate according to the seriousness of the complaint and if they meet our current protocol.

.....

“On this occasion we have decided that a criminal investigation is not appropriate and as the

trader is outside of Nottinghamshire the trading standards department relevant to the trader will have been informed if you have already reported this through the Citizens Advice Consumer Service.”

Lambeth TS office replied as follows:

“I have referred both of your complaints to Hertfordshire Trading Standards, as the traders are based there.

“Additionally, in order to put multi-agency pressure on these traders and their selling techniques, I would like to ask that you contact your professional body (GMC?) and also Hertfordshire Public Health.”

In both cases, nothing was heard from any other TS office.

The full text of all TS responses is to be found in section 18.2 on page29. Note that relatively few substantive responses were received, only 16 in response to 38 complaints submitted.

14 Discussion

This study demonstrates that making complaints to the statutory authority Trading Standards (TS) about misleading health-related claims is neither easy nor effective. The study ran for far longer than planned because most of the investigators, who were all unpaid volunteers, found the process too time-consuming. This process had been designed according to legal advice commissioned by the sponsor HealthWatch, and the key components were:

- to give the trader the opportunity to provide evidence for the claims
- to issue a cease and desist letter if such evidence was lacking
- to use specific wording when sending a complaint to Trading Standards
- to follow up the complaint with a more detailed letter, again using specific wording

A primary focus of the study was the Consumer Protection from Unfair Trading Regulations 2008, and the above process was structured to encourage TS offices to use this legislation. The process largely failed to do this. Three quarters of our volunteers, all of whom were keenly interested in the study, did not manage to make any complaints at all. The average consumer will be far less likely to challenge misleading claims, so it is hardly surprising that most such claims are made with impunity.

Because of the difficulty investigators had with submitting complaints, and the inevitable drop-outs, the data available for analysis are very incomplete. Nevertheless some outcomes are identifiable, and these fall into two main areas; enforcement action taken, and TS responses.

14.1 Enforcement Action Taken

Firstly, very little enforcement action by TS could be detected. When TS offices did respond, they took an overall median of six weeks to do so, but this varied greatly between the claims being challenged. For Halcyon Bracelets the median response time was 15 weeks. However many of these responses only occurred after investigators prompted TS offices, and this could only happen if they had the contact details. It should be explained that Citizens Advice operates on the basis of simply passing complaints to the appropriate TS office. On enquiry, investigators were told that they would only hear from TS if further information was required. The problem therefore is that if nothing is heard, it is impossible to know the reason. It might be because nothing is being done, or it might be because action is being taken and no further information is required. When presented with this dilemma, Citizens Advice had no comment.

14.2 Trading Standards Responses

While the data show how ineffective TS offices were, the written responses they provided may shed some light in the reasons for this. The statement “We would need to prove that a claim is false or misleading beyond reasonable doubt...”, as provided by Wiltshire TS office, suggests that they have misunderstood the way the law works. It is true that TS has to apply a more onerous standard to evidence than does the ASA. This is because they are essentially preparing the ground for prosecution. They have to have a case that has a good prospect of securing a conviction in court. However they imply that this means that they do not ask the advertiser for evidence, and then test the evidence for validity. TS apparently goes directly to expert witnesses for opinions on the claims. This confusion may arise from two definitions of the word ‘evidence’. That used by TS is the evidence that an offence has been committed. Clearly it is the responsibility of TS to provide that evidence. The other definition is that of the substantiation of an advertising claim. It is beyond

dispute that the advertiser bears the responsibility for that.

Camden TS office agreed to act as the ASA's legal backstop in 2013. Hence the ASA has an online list of non-compliant advertisers who have been referred to TS for possible prosecution. We were therefore surprised when TS directed us to the ASA as 'established means' of enforcement of the CPRs. We have been unable to clarify the legal status of this 'established means', ie on whose authority it was established. Obviously this creates a circular process, although we are not yet aware of any of the ASA's non-compliers having been referred back again. As TS has to reach a higher threshold for a prosecution, it therefore seems unlikely that it can operate effectively as the ASA's legal backstop. In most cases an advertiser adjudged non-compliant by the ASA would not be disciplined by TS. This is a possible area for further research.

14.3 Further Legal Advice, and Implications

The responses from TS that arose in this study prompted us to seek further legal advice. We understand that as a statutory body TS has to follow certain enforcement standards and codes. If a TS officer has reasonable grounds to suspect an offence is committed they must also have regard to other issues such as proportionality and the guidelines on criteria for prosecutions, and only bring a prosecution (or formal enforcement) if:

- (i) there is a realistic prospect of a conviction (the 'evidential test'); and
- (ii) it would be in the public interest (the 'public interest test').

For the first of these, the evidential test is passed if the advertiser fails to provide valid evidence for their claim. Yet Wiltshire TS stated that they "have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed". In this study, we provided such "reasonable grounds". We asked the advertiser for evidence for their claim, we demonstrated persistent offending by issuing 'cease and desist' letters, and we sent TS detailed explanations of why the claim was invalid and why it would cause a consumer to make a bad decision.

Public interest is a matter of judgement. It may well be that TS officers do not consider that sufficient harm is done by misleading health claims. Such a misconception is very easily refuted; there is ample evidence of real harm, including death, caused to people who eschew real medical care in favour of the false promises of alternative health practitioners⁴.

Our legal advice pointed out that the ASA is far more likely to investigate a complaint than is TS, simply because the former specialises in advertising. TS has a much wider remit and hence there is more internal competition for time and resources. TS offices are operated and funded by local government, and varying resource across the UK could account for large differences in priorities between offices, as we observed. Indeed, this resourcing problem is recognised by central government. A report by the National Audit Office states in its summary⁵ that, while consumer protection is operated at local level, commerce has changed and is far more national and international. Thus "the scale and sustainability of the response at the national level is limited relative to the problem being tackled and system-wide prioritisation of resources is difficult within the current arrangements". TS offices are now working with fewer than half the personnel of the year 2001⁶. Local priorities are likely to be heavily skewed by varying demands.

But while TS offices have the option to decide their own priorities, they have a duty to enforce the law, and must operate on a case by case basis. Any suggestion that they systematically decline to deal with the regulation of any sector would be objectionable. In our study, of 38 complaints submitted to TS we could only identify enforcement action for four of them. TS exercised its right to use other "established means" of enforcement, by referring two complaints to the Medicines and

Healthcare products Regulatory Agency (MHRA). No action was taken by the MHRA. One such case was of a homeopath. The MHRA was probably correct in referring this back to TS, because it can only regulate homeopathic products rather than homeopathy as a practice. Nevertheless it does again demonstrate the reluctance of TS to deal with complaints, as well as its misunderstanding of the MHRA's remit. The other such complaint was about an electronic device, and the lack of MHRA action has been fully described elsewhere³. It is notable that the MHRA refused to divulge any information, even whether they were actually investigating the claims being made, citing commercial confidentiality under the Enterprise Act.

An interesting new finding in this study was that several traders quickly removed their claims from their websites. This did not happen in the pilot study. Some claims were reinstated later, but it does show that these traders probably were well aware of the lack of evidence for their claims. The conclusion is that it is worth asking for evidence, and may be more effective than complaining to TS.

14.4 Study Limitations

The main limitation of this study was the large number of missing data points. The principal cause of this was the difficulty of communicating with TS, and the withdrawal of so many investigators. We planned to submit 100 complaints, but only submitted 38. Follow-up of complaints generated few data, for the reasons given above, again principally because of the difficulty of communicating with TS.

We do not know if our dataset represents a valid sample of TS operations across the UK. However such was the workload in this study, that it does not seem practicable to commit to a larger one.

15 Conclusions

Submitting complaints to Trading Standards regarding misleading health-related claims is extremely labour-intensive and does not encourage vigilance by consumers.

Most complaints to Trading Standards regarding misleading health-related claims do not attract any enforcement action.

Approaches to enforcement among Trading Standards offices are highly variable, showing little or no standardisation.

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17 Conflict of Interest Statement

No member of the study team, including the authors, has any material connection with any of the organisations investigated in this study.

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Table 1: Claims selected for assessment

Trader	Website	Product/Service	Claims
Halcyon Bracelets	http://www.halcyonbracelets.com/	Copper Bracelets	Restless legs Note: GRCCCT ¹ accredited, claiming: “Halcyon Bracelets website meets the strict industry standards and requirements of law for online advertising in this field.”
Hautman Homeopathy	http://www.hautmanhomeopathy.com	Homeopathy	Patients seeking to use homeopathy often come with conditions that have not responded to other forms of treatment, including: Skin complaints - eczema, psoriasis, rashes, warts, acne, dermatitis, fungal infections Digestive disorders - bloating, heartburn, colitis, IBS, Crohn's disease, constipation, diarrhoea, food poisoning Respiratory disorders - asthma, recurrent infections, Auto-immune disorders - allergies, arthritis, rheumatism Mental and emotional complaints - depression, stress, anxiety, panic attacks, phobias, grief, PTSD, anger, low self esteem, lack of confidence, insomnia, fears, night terrors, OCD Men's health - stress, anxiety, over-exertion, infertility, prostate problems, erectile dysfunction Women's health - menstrual and hormonal problems, PMS, thyroid problems, infertility, cystitis, candida, fibroids, polycystic ovaries, PCOS, pregnancy and birth complaints, birth trauma, pre and post natal depression, breastfeeding and lactation difficulties, menopause Childhood diseases - fevers, colic, teething, mumps, measles, whooping cough, chicken pox etc Behavioural difficulties - bed-wetting, tantrums, aggression, hyperactivity, ADD, ADHD, autism, aspergers, dyslexia, dyspraxia Other debilitating conditions - injuries, accidents, traumas, surgery, migraines, headaches, backache, chronic fatigue, CFS, ME
The Crystal Healer	http://www.thecrystalhealer.co.uk/	Crystals	EG: Red jasper helps to prevent illness, enhances psychic protection and is especially powerful against witch craft when combined with jet. Red jasper promotes re-birth, new ideas, astral travel, meditation, your basic survival instinct and dream recall. Perhaps red jasper's best attribute is as an all round tonic for the body helping to both heal and prevent minor illness such as colds and flu.
The Wellbeing Clinic	http://www.thewellbeingclinic.org/colonic.html	Colonic hydrotherapy	Are Colonics safe? Yes, perfectly. Chronic Back Pain: A colon that is heavily impacted with waste is not only poisoning the system, but also contributing to back problems by putting pressure on the sciatic & lumbar nerves. This situation unfortunately is universally overlooked. Parasites and worms can also cause backache. Colon Cancer: This is the second leading cause of death, which is an exclusive phenomenon of the Western World, with the highest rate in the U.S.A. Colon cancer is directly linked to high animal protein and low fibre. Addictions: By cleaning the colon and removing poisons, this aids in eliminating the addiction in a less traumatic way with less side effects. Some of the ailments that can be eliminated with Colon Therapy: Joint pains, high blood pressure, high cholesterol, hormone imbalances, irritable bowel, constipation, diarrhoea, liver & gallbladder problems, PMS, arteriosclerosis, yeast problems & candida, diabetes, cellulite, acne, immune deficiency and addictions. Carcinogens: Periodic colon cleansing reduces the colon walls' susceptibility to carcinogens.

1. General Regulatory Council for Complementary Therapies

Trader	Website	Product/Service	Claims
Wendy Hooper	http://www.wendyhooper.co.uk/colonic.htm	Colonic hydrotherapy	Original claims: Constipation, diarrhoea, IBS, colitis, diverticulitis, sinusitis, halitosis, headaches, flatulence, haemorrhoids, skin conditions, bloating, asthma, allergies, fatigue and many emotional states such as depression and lethargy are also helped by the resultant detoxifying effects.
Amazing Health	http://www.amazinghealth.co.uk/magnetic-therapy.html	Magnets for pain	Magnetic healing has been used in conventional medical practice as a form of pain relief for some time now which emit electro magnetic fields, EMF's and similar technology has been incorporated into magnetic therapy bracelets, but without the harmful radiation.
Weleda	http://www.weleda.co.uk/circulation/massage-cup/inv/409175	Massage Cup	Improve circulation, combat cellulite and ease muscular tension with cup massage, an ancient technique that stimulates blood flow and lymph drainage to leave you with smooth healthy skin. Use with Birch Cellulite Oil for holistic detoxification.
Get FITT Ltd	http://www.getfitt.com/fatigue.htm	Far Infrared Sauna Therapy For Fatigue & Chronic Fatigue Syndrome	Studies have shown that Far Infrared Thermal Therapy may be a promising approach for Chronic Fatigue Syndrome treatment.
Asyra	http://www.asyra.co.uk/wp-content/uploads/2014/06/asyra_brochure.pdf	Electro-dermal screening machine	By testing for thousands of nutritional factors, homeopathic remedies, cell salts, herbs, nosodes for bacteria, viruses, parasites, fungi and much more – the Asyra delivers a picture of health status and how to improve it in moments.
Christine Wilson - homeopath	http://www.lovelyhealth.co.uk/allergy.html	Vega testing	<p>Basic Vega Test</p> <p>The Basic Vega Test is for up to 245 different food substances however, some people notice that their symptoms are related to particular brands of foods, drinks etc and if this is the case you are welcome to bring along any store cupboard ingredients suspected of causing problems in glass or plastic containers. It would also be helpful if you could bring the original packaging in order that the ingredients can be assessed.</p> <p>Additional Tests</p> <p>Environmental substances This test looks for sensitivities to 53 environmental substances including pollens, fabrics, animal hair, dust etc.</p> <p>E-numbers This test looks for sensitivities to 64 E-numbers including colouring, preservatives, sweeteners, stabilisers, antioxidants, flavour enhancers etc.</p> <p>Vitamin and Mineral Deficiencies This test looks for deficiencies in 19 vitamins and 15 minerals.</p> <p>Hormone Deficiencies This test looks for deficiencies in 30 hormones.</p> <p>Organ Imbalances This test looks for imbalances in 72 different parts of the body including heart, lungs, liver, pancreas, stomach, intestines, reproductive organs, some blood vessels and nerves and some parts of the brain.</p>

Table 2: Study disposition

Investigator ID	Local authority region¹	Requests for evidence²	Comment
01	London Borough of Southwark	2	
02	Nottingham	5	
03	London Borough of Merton	2	
04	Oxford	6	
05	North Yorkshire	9	
06	West Yorkshire	5	Investigator withdrew, no complaints made
07	Nottingham	3	
08	London Borough of Lambeth	2	
09		5	Investigator withdrew, no complaints made
13	Wiltshire	5	
14	Brighton	5	
15	London Borough of Lambeth	6	
16	London Borough of Merton	7	
17		7	Investigator withdrew, no complaints made
18	Stratford on Avon	10	
Total requests		79	

1. Local authority regions are not complete because of investigator drop-outs and non-responders

2. Number varies because some traders removed claims.

Table 3: Interactions with traders

Trader	Requests for evidence n	Responses from trader n (%) ¹	Evidence provided ²	Claims removed after request for evidence	Cease & desist letters n (%) ³	Claims removed after C&D letter n ⁴
Halcyon Bracelets	12	5 (42)			8 (67)	
Hautman Homeopathy	8	0 (0)			7 (88)	
The Crystal Healer	9	2 (22)			7 (78)	
The Wellbeing Clinic	8	1 (13)		Yes	4 (50)	Yes
Wendy Hooper	5	0 (0)			5 (100)	Yes
Amazing Health	5	4 (80)		Yes	4 (80)	Yes
Weleda	5	2 (40)		Yes	2 (40)	
Get FITT Ltd	10	5 (50)	3		7 (70)	Yes ⁵
Asyra	7	2 (29)			5 (71)	
Christine Wilson - homeopath	10	1 (10)	1		6 (60)	
Totals	79	22 (28)	4	3	55 (70)	4

Notes

1. Percentage of requests for evidence which drew a response.
2. No evidence was valid.
3. Percentage of requests for evidence which were followed by a cease and desist letter.
4. It is not possible to assign claim removal definitely to either request for evidence or cease and desist letter.
5. Claims were rapidly reinstated and expanded.

Table 4: Interactions with Trading Standards

Trader	Total Complaints to Citizens Advice	Responses from Citizens Advice n (%) ⁴	Responses from Trading Standards n (%) ⁴	Median time to Citizens Advice response Working days ¹	Median time to Trading Standards response Working days ¹
Halcyon Bracelets	7	5 (71)	4 (57)	2	74
Hautman Homeopathy	5	3 (60)	1 (20)	99	31
The Crystal Healer	8	7 (88)	5 (63)	3	17
The Wellbeing Clinic	3	3 (100)	3 (100)	2	30
Wendy Hooper ²	-	-	-	-	-
Amazing Health	2	1 (50)	1 (50)	1	10
Weleda ²	-	-	-	-	-
Get FITT Ltd	8	6 (75)	1 (25)	4	36
Asyra	4	3 (75)	3 (75)	3	17
Christine Wilson - homeopath ³	1	0 (0)	0 (0)	-	-
Totals	38	28 (74)	18 (53)	3	31

1. Of those that responded
2. Claims removed – no further action taken.
3. All investigators but one assigned to this trader withdrew after sending requests for evidence.
4. Because of missing data, the percentages are not calculated with the numbers of complaints as denominator. Only known data are included.

Table 5: Complaint follow-up

Trader	Initial follow-up letters by study team	Follow-up contacts from Trading Standards	Follow-up contacts by study team	Comment
Halcyon Bracelets	10	7	6	
Hautman Homeopathy	8	5	3	
The Crystal Healer	4	10	12	
The Wellbeing Clinic	0	2	1	Claims removed after first complaints
Wendy Hooper	1	0	1	
Amazing Health	10	3	7	
Weleda	0	0	0	Claims removed, no action.
Get FITT Ltd	1	4	8	
Asyra	6	3	3	
Christine Wilson - homeopath	6	1	2	
Totals	46	35	43	

Table 6: Complaint outcomes by claim

Trader	Trader complied with TS, claims removed	TS advised trader, but trader did not comply	Case referred to another regulator	TS prosecuted trader.	Total enforcement actions n	TS took no action n	TS action not resolved at study end
Halcyon Bracelets					0	1	
Halcyon Bracelets					0		1
Halcyon Bracelets					0	1	
Hautman Homeopathy					0	1	
The Crystal Healer					0	1	
The Crystal Healer					0	1	
The Crystal Healer	1				1		
The Crystal Healer	1				1		
The Wellbeing Clinic	1				1		
The Wellbeing Clinic	1				1		
The Wellbeing Clinic					0		
Wendy Hooper					0		
Wendy Hooper					0		
Amazing Health					0		1
Weleda					0		
Get FITT Ltd					0	1	
Get FITT Ltd					0	1	
Get FITT Ltd					0	1	
Asyra			1		0		
Asyra					0		
Asyra					0	1	
Christine Wilson - homeopath			1		0		
Total count	4	0	2		4	9	2

Counts are expressed as reported by investigators. Trading Standards did not always notify investigators of outcomes, hence many data points are missing.

Counts are affected by:

- Traders removing and then reinstating claims
- Traders only removing claims after multiple contacts
- Different TS offices acting differently.

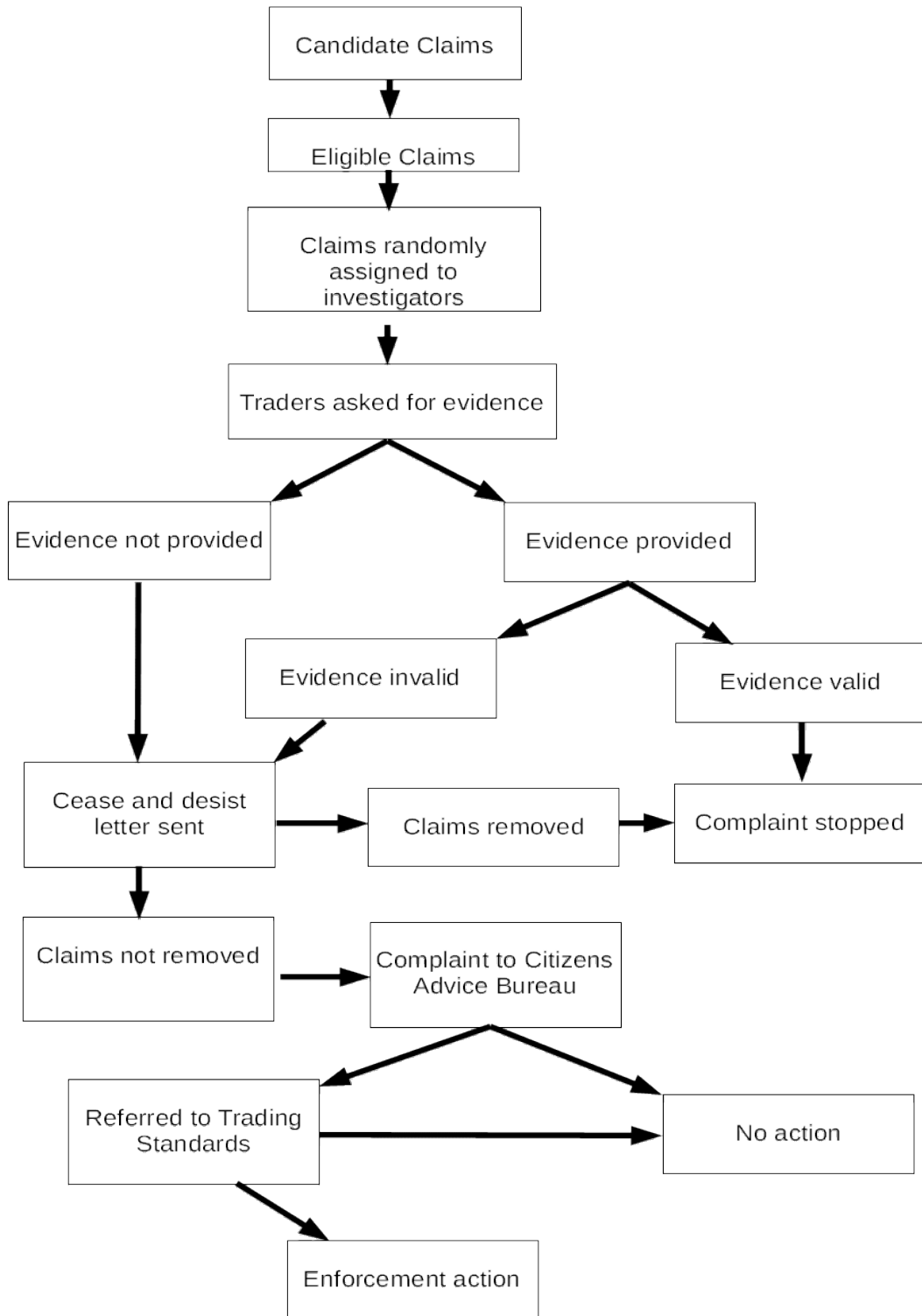
Table 7: Complaint outcomes by Trading Standards region

TS Region	Number of complaints ¹	Trader complied with TS, claims removed	TS advised trader, but trader did not comply	Case referred to another regulator ²	TS prosecuted trader.	Total enforcement actions	TS took no action	TS action not resolved at study end
London Borough of Southwark	2					0	2	
Nottingham	9	2				2	4	
London Borough of Merton	8					0		2
North Yorkshire ²	2			2		0		
London Borough of Lambeth	7	1				1	1	
Wiltshire	4	1				1	2	
Totals	34	4	0	2	0	4	9	2

1. 4 complaints not assigned to a TS region because investigators withdrew.

2. 2 complaints referred to the MHRA.

Figure 1: Study flow chart



18.2 Trading Standards responses

The full text responses from Trading Standards (TS) are tabulated here. Only substantive responses are included; simple acknowledgements etc are omitted. Personal information has been redacted.

Trader	TS Region	TS response Text
1	Wiltshire	<p>I have been passed details of the complaints that you have made about the above 3 websites by the Citizens Advice Consumer Service. I have looked at the 3 websites and would like to make the following comments.</p> <p>www.asyra.co.uk and www.halcyonbracelets.com are both making specific claims about specific products. Trading Standards are not best placed to determine the accuracy or otherwise of these claims and have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed. We would need to prove that a claim is false or misleading beyond reasonable doubt before we could consider taking any formal action. However, the Advertising Standards Authority (ASA) now has marketing on companies' own websites, as well as external advertising, within their remit. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. Consequently you may wish to refer your concerns about any specific claims on these websites to the ASA.</p> <p>www.thecrystalhealer.co.uk is also making claims and so my advice to you regarding the majority of these would be the same as above. However, they are also making references to cancer in the 'healing qualities' section of the information listed against certain crystals which may possibly breach the provisions of the Cancer Act 1939. I will look into this aspect in more detail and liaise with my colleagues in Hertfordshire Trading Standards (where the ownership of the website appears to be based) to ensure that the business is advised appropriately with regard to this legislation.</p> <p>For your information, my colleague, [REDACTED], has been allocated your complaint about the Wellbeing Clinic in Marlborough.</p> <p>Thank you for drawing this matter to our attention. If you have any queries on what I have said then please come back to me.</p>
1	Merton	<p>Having considered this complaint I am of the opinion that the information provided on the website is simply experience of the seller. Seller has suffered with RLS for a long time and discovered that a particular bracelet containing a specific copper was providing tremendous relief. Seller modified the original bracelet and today sells a pair as Halcyon Bracelets. I do not consider the information to be an infringing CPRs and seller does not claim any defined cure or treatment benefits but remedy to sufferers based on her experience. She offers money back after 4 weeks use if the bracelets do not offer the buyer the same relief.</p>
1	Merton	<p>Thank you for your recent correspondence.</p> <p>Please find a ruling by the Advertising Standards Authority with regard to the Halcyon Bracelets at https://www.asa.org.uk/Rulings/Adjudications/2015/2/Halcyon-Bracelets/SHP_ADJ_279436.aspx</p> <p>Essex Trading Standards are currently considering the matter in light of current advertising and ASA ruling."</p>
1	Merton	<p>We have received details of your email correspondence with regard to the alleged false claims, from our partners - the Citizens Advice Consumer Service.</p>

Trader	TS Region	TS response Text
		I am aware of the website. Another Merton resident raised similar concerns. I will come back to you in due time with an update once I have discussed the matter with Essex Trading Standards.
3	Wiltshire	<p>I have been passed details of the complaints that you have made about the above 3 websites by the Citizens Advice Consumer Service. I have looked at the 3 websites and would like to make the following comments.</p> <p>www.asyra.co.uk and www.halcyonbracelets.com are both making specific claims about specific products. Trading Standards are not best placed to determine the accuracy or otherwise of these claims and have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed. We would need to prove that a claim is false or misleading beyond reasonable doubt before we could consider taking any formal action. However, the Advertising Standards Authority (ASA) now has marketing on companies' own websites, as well as external advertising, within their remit. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. Consequently you may wish to refer your concerns about any specific claims on these websites to the ASA.</p> <p>www.thecrystalhealer.co.uk is also making claims and so my advice to you regarding the majority of these would be the same as above. However, they are also making references to cancer in the 'healing qualities' section of the information listed against certain crystals which may possibly breach the provisions of the Cancer Act 1939. I will look into this aspect in more detail and liaise with my colleagues in Hertfordshire Trading Standards (where the ownership of the website appears to be based) to ensure that the business is advised appropriately with regard to this legislation.</p> <p>For your information, my colleague, [REDACTED], has been allocated your complaint about the Wellbeing Clinic in Marlborough.</p> <p>Thank you for drawing this matter to our attention. If you have any queries on what I have said then please come back to me.</p>
3	Merton	The claims being made could be considered definitive and specific in relation to the prevention of illness and treatment of bone cancer, AIDS and multiple sclerosis. I referred your concerns and results of my investigation to the local trading standards where Philip Permutt, The Crystal Healer is based. The trading standards service is aware of the trader and an officer is advising him. He is in the process of taking these claims down.
3	Nottinghamshire	<p>Each year this Service receives thousands of complaints and our most effective response is to prioritise those we directly investigate according to the seriousness of the complaint and if they meet our current protocol.</p> <p>Our current protocol has been developed to protect the most vulnerable consumers from consumer detriment and to ensure that legitimate businesses in the Nottinghamshire area have a fair trading environment by targeting the most serious rogue traders operating within our boundaries.</p> <p>There will as a consequence be some complaints that are not directly investigated, but in all instances the information is recorded on our database and retained for future reference. This information assists us in identifying the traders, trade sectors and legislative areas that we need to focus our attention on. We can then work proactively to prevent similar problems occurring in the future.</p> <p>On this occasion we have decided that a criminal investigation is not appropriate</p>

Trader	TS Region	TS response Text
		<p>and as the trader is outside of Nottinghamshire the trading standards department relevant to the trader will have been informed if you have already reported this through the Citizens Advice Consumer Service. Thank you for bringing this matter to our attention and I can assure you that we will make the most effective use of the information provided</p>
3	Lambeth	<p>Thank you for contacting Trading Standards.</p> <p>I have referred both of your complaints to Hertfordshire Trading Standards, as the traders are based there.</p> <p>Crystal Healer (www.thecrystalhealer.co.uk) 1 Verulam Industrial Estate London Road St Albans Hertfordshire AL1 1JB</p> <p>...and</p> <p>Get-fit Get Fitt Limited (www.get-fitt.com) 31 Christchurch Crescent Radlett Hertfordshire WD7 8AQ</p> <p>Additionally, in order to put multi-agency pressure on these traders and their selling techniques, I would like to ask that you contact your professional body (GMC?) and also Hertfordshire Public Health (http://www.hertsdirect.org/your-council/hcc/publichealth) and inform them of your concerns.</p>
3	Lambeth	<p>Thank you for contacting Trading Standards.</p> <p>I have referred both of your complaints to Hertfordshire Trading Standards, as the traders are based there.</p> <p>Crystal Healer (www.thecrystalhealer.co.uk) 1 Verulam Industrial Estate London Road St Albans Hertfordshire AL1 1JB</p> <p>...and</p> <p>Get-fit Get Fitt Limited (www.get-fitt.com) 31 Christchurch Crescent Radlett Hertfordshire WD7 8AQ</p> <p>Additionally, in order to put multi-agency pressure on these traders and their selling techniques, I would like to ask that you contact your professional body</p>

Trader	TS Region	TS response Text
		(GMC?) and also Hertfordshire Public Health (http://www.hertsdirect.org/your-council/hcc/publichealth) and inform them of your concerns.
4	Wiltshire	I have been in contact with the Wellbeing Clinic, Marlborough and their website has now been amended.
4	Wiltshire	Following advice from ourselves, the Wellbeing Clinic has removed any health claims from its website which we would be concerned about. We will not be taking your complaint any further. I have advised your associates of this who appear to be satisfied with the website in its current format.
4	Merton	<p>The Wellbeing Clinic, 6 London Road, Wiltshire, SN8 1PH</p> <p>I have now had a chance to look at the webpage under Colonic Hydrotherapy - http://www.thewellbeingclinic.org/teresam.shtml. I would be grateful for some clarity on the specific health claims you are referring to.</p> <p>In general according to the NHS choices website or the Association of Registered Colon Hydrotherapists, the UK's leading community for colon hydrotherapists or findings of the Advertising Standards Authority, there is no scientific evidence to suggest there are any health benefits associated with Colonic Hydrotherapy. With this in mind therapists cannot make any definitive medical claims whether by specific wording or implication.</p> <p>I look forward to hearing from you.</p>
6	Merton	<p>Consumer Protection from Unfair Trading Regulations 2008</p> <p>We have received details of the complaint you made to the Citizens Advice Consumer Service. Kindly let me have examples of information on the website which you consider to be misleading in the absence of evidence from the trader. In addition please send me copies of the email correspondence with the trader.</p>
8	Lambeth	<p>Thank you for contacting Trading Standards.</p> <p>I have referred both of your complaints to Hertfordshire Trading Standards, as the traders are based there.</p> <p>Crystal Healer (www.thecrystalhealer.co.uk) 1 Verulam Industrial Estate London Road St Albans Hertfordshire AL1 1JB</p> <p>...and</p> <p>Get-fit Get Fitt Limited (www.get-fitt.com) 31 Christchurch Crescent Radlett Hertfordshire WD7 8AQ</p> <p>Additionally, in order to put multi-agency pressure on these traders and their selling techniques, I would like to ask that you contact your professional body (GMC?) and also Hertfordshire Public Health (http://www.hertsdirect.org/your-council/hcc/publichealth) and inform them of your concerns.</p>

Trader	TS Region	TS response Text
9	Wiltshire	<p>I have been passed details of the complaints that you have made about the above 3 websites by the Citizens Advice Consumer Service. I have looked at the 3 websites and would like to make the following comments.</p> <p>www.asyra.co.uk and www.halcyonbracelets.com are both making specific claims about specific products. Trading Standards are not best placed to determine the accuracy or otherwise of these claims and have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed. We would need to prove that a claim is false or misleading beyond reasonable doubt before we could consider taking any formal action. However, the Advertising Standards Authority (ASA) now has marketing on companies' own websites, as well as external advertising, within their remit. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. Consequently you may wish to refer your concerns about any specific claims on these websites to the ASA.</p> <p>www.thecrystalhealer.co.uk is also making claims and so my advice to you regarding the majority of these would be the same as above. However, they are also making references to cancer in the 'healing qualities' section of the information listed against certain crystals which may possibly breach the provisions of the Cancer Act 1939. I will look into this aspect in more detail and liaise with my colleagues in Hertfordshire Trading Standards (where the ownership of the website appears to be based) to ensure that the business is advised appropriately with regard to this legislation.</p> <p>For your information, my colleague, [REDACTED], has been allocated your complaint about the Wellbeing Clinic in Marlborough.</p> <p>Thank you for drawing this matter to our attention. If you have any queries on what I have said then please come back to me.</p>
9	North Yorkshire	(Response by telephone): TS officer will discuss the complaint with MHRA and report back to me as to what they advise.
9	Merton	I understand from the website that this system is intended for use by alternative therapy practitioners and it would appear it is being marketed as able to perform in a way it was never intended. I have discussed the matter with Medicines and Healthcare products Regulatory Agency and am still waiting for replies on a couple of correspondences. I will come back to you with an update in due time.

18.3 Legal Advice received

18.3.1 Pre-study Advice

Background

We have been asked by HealthWatch to advise and consider the enforcement of the Consumer Protection from Unfair Trading Regulations 2008 ("CPR"). In particular we have been asked to consider 10 specific questions.

Legal Questions and Answers

These questions are outlined below. Our response is contained beneath each question.

- 1. We propose to submit complaints to Trading Standards complaints about false claims for health benefit made by advertisers of products and services. We will avoid products that could be classed as foods, to ensure that food legislation can't be used. What legislation could Trading Standards choose to handle - or evade - our complaints, and in what priority?**

By way of context it's important to be aware that the CPRs transpose the provisions of Directive 2005/29/EC on Unfair Commercial Practices ("the Directive"). The Directive constitutes the main general body of EU legislation regulating misleading advertising and other unfair practices in business-to-consumer transactions. It has a broad scope of application, applying to all business-to-consumer transactions and in all sectors. However although the Directive provides for a high level of consumer protection in all sectors, it is important to be aware that it works as a safety net which fills the gaps which are not regulated by other EU sector-specific rules.

This means that where there is product-specific legislation that deals with misleading claims on pack and in advertising then the product-specific legislation applies. For example, legislation for cosmetics and foods both address misleading claims so it would be expected that these particular pieces of legislation would be used to enforce issues relating to misleading claims for these products. However in the case of medical devices although there is specific legislation it does not address misleading claims, which would mean that the CPRs would apply if a misleading health claim was made in respect of such a product.

Therefore from Trading Standards' perspective it is necessary to determine if the product or service in question has specific legislation which regulates it and if so whether it addresses the issue of misleading claims. Another complicating factor when it comes to health claims is the nature of the claim. If the health claim is so strong as to be a medicinal claim then primacy for enforcing the legislation will fall to the MHRA.

The scale, or scope, and criminality are also factors that need to be considered as other criminal offences may also be relevant (offences under the Fraud Act 2006 and conspiracy to defraud). In practical terms, the CPR impose a high evidential bar as to what is misleading, in particular the definition of a misleading action under Regulation 5. Each case turns on its own facts and there is no case law for guidance, for example to define the transaction behaviour of 'the average consumer'. Many local authorities are reluctant to devote resources to enforcement through criminal process or CPR, despite being under a duty to investigate offences under CPR. In the absence of any complaint other than through the complainant (and complaints by pressure or industry groups might be regarded as being

worthy but not necessarily evidence pertaining to the “average consumer”, where there appears to be false or misleading advertising (such that the CAP codes apply), Trading Standards take the easy route and refer to ASA.

Some insight is provided by the recent *Review of the enforcement provisions of the Consumer Protection from Unfair Trading Regulations 2008 in respect of copycat packaging – call for evidence* issued by the Department for Business Innovation and Skills, where reference was made to the Hampton Principles.¹ This was given as justification for first attempting to stop the violation through discussions with the trader, rather than automatically applying for a court order. Therefore, if the trader were to provide an undertaking not to engage in the activity this may be regarded as being sufficient (in the circumstances of those categories of offence).

The weakness with this position is that accountability, proportionality, transparency, targeting and consistency are all factors that need to be considered in weighing up the appropriate means of enforcement. Likewise whether, assuming there is a reasonable prospect of conviction, a prosecution is in the public interest.

Put simply, there is room to hold Trading Standards to account either to their own enforcement policies (which may or may not provide a codified approach to offences under the CPR) and/or wider principles of enforcement.

In extreme cases, a decision not to prosecute is capable of being judicially reviewed although we would canvass that this is a very expensive option and subject to the caveat that most decisions whether to take action or to prosecute are based on the principle of discretion.

It is therefore our view that where there is not product-specific legislation which applies and the health claims are not medicinal the most pragmatic option is to hold Trading Standards to their own principles of enforcement and to make their job as easy as possible by directing them, where such evidence exists, to factors which would positively influence a decision to prosecute. These include:

- whether the offending is persistent, despite previous advice to desist;
- the vulnerability of the victims; and
- whether there is significant risk to public health and safety or to the environment.

For these purposes, we also suggest that, as well as preparing a dossier to submit to Trading Standards, a cease- and desist-type letter is sent to the offending trader. This would have the evidential advantage that, where the offending advertising nonetheless continues, it is capable of being regarded as deliberate or reckless which would not only influence a decision to prosecute but could also broaden the scope of offences available.

There is no legislation through which a prosecution can be avoided. However, their view (driven by policy and resource constraints) is that taking alternative action is not evading the complaint so much as enforcing through another means.

2. We have previously found that Trading Standards officers claimed that they had to use ‘primary legislation’, defined in guidance they had received from the Office of Fair Trading. TSOs defined this as legislation specific for a product group, and was their justification for not using the CPUTRs. When asked, the OFT could not identify any such guidance. Are not aware of any definition of ‘primary legislation’ in this context?

As stated above where there is specific product legislation this will be the appropriate legislation to enforce. We suspect that it is product-specific legislation which Trading Standards refer to as ‘primary legislation’. This distinction between product-specific and legislation and CPRs as gap-filling legislation is a distinction made at EU level.

¹“Reducing Administrative Burdens: Effective Inspection and Enforcement”, Philip Hampton, HM Treasury, March 2005.

3. **We do not understand the concept of 'established means' of enforcing the CPUTRs; can you explain? In the previous study, TS officers considered that using older food standards regulations were the 'established means' for enforcing the CPUTRs. Again, this meant that they refused to apply the Regulations.**

Regulation 19 of the CPR refers to "established means". This essentially means ways of addressing the matter other than under the CPR. For instance, this could refer to specific product legislation or it could refer to the ASA which may in certain circumstances be considered to be the more appropriate authority to deal with the complaint, as they have informal means by which to deal with advertising complaints.

This goes back to the point raised in the response to question 1, that the threshold of what is misleading is quite high, therefore there may be clearer and more obvious breaches under other Regulations which would be easier to make out and lead to the same consequence.

4. **Trading Standards Officers assess complaints on the basis of the 'average consumer'. They informed us that as activists specialising in health care we are not average consumers and therefore our complaints do not represent the general public. Is this a fair defence? It seems to reduce the 'average consumer' to a patsy to be gulled. Might we be seen as 'agents provocateurs'? And does this matter?**

Primarily the offence that you appear to be most concerned with is Regulation 5 of the CPR. This requires that either the criteria of Regulation 5(2) or 5(3) are met. Both of these contain the 'average consumer' test whereby "it causes or is likely to cause the average consumer to take a transactional decision he would not have taken otherwise". In Regulation 5(3) there is an additional caveat as discussed later.

The 'average consumer' is defined under the CPR. 'Consumer' is defined in Regulation 2 as "any individual who in relation to a commercial practice is acting for purposes which are outside his business".

An 'average consumer' is to be construed in line with Regulation 2(2) to 2(6):

"(2) In determining the effect of a commercial practice on the average consumer where the practice reaches or is addressed to a consumer or consumers account shall be taken of the material characteristics of such an average consumer including his being reasonably well informed, reasonably observant and circumspect.

(3) Paragraphs (4) and (5) set out the circumstances in which a reference to the average consumer shall be read as in addition referring to the average member of a particular group of consumers.

(4) In determining the effect of a commercial practice on the average consumer where the practice is directed to a particular group of consumers, a reference to the average consumer shall be read as referring to the average member of that group.

(5) In determining the effect of a commercial practice on the average consumer—

(a) where a clearly identifiable group of consumers is particularly vulnerable to the practice or the underlying product because of their mental or physical infirmity, age or credulity in a way which the trader could reasonably be expected to foresee, and

(b) where the practice is likely to materially distort the economic behaviour only of that group,

a reference to the average consumer shall be read as referring to the average member of that group.

(6) Paragraph (5) is without prejudice to the common and legitimate advertising practice of making exaggerated statements which are not meant to be taken literally."

Trading Standards are correct in identifying the 'average consumer' issue on the basis that this forms an element of the offence. Nonetheless, it is not a requirement that an average consumer is the one to raise the complaint. Someone with specialist knowledge can raise

the complaint. The evidential requirement, however, is different because it requires that the offending behaviour be likely to cause an average consumer to take a transactional decision they would not have taken otherwise. Regulation 5(3) is slightly more specific than this as it also requires that the factual context and all the features and circumstances also be taken in to account.

What this could mean is that if HealthWatch conducted a study, everyone within that study could be considered to be imbued with more knowledge than a typical consumer. However, it does not necessarily follow that because of this the average consumer is gullible, as an average consumer has certain qualities attributed to them; so they are considered to be reasonably well informed as per Regulation 2(2).

5. In the previous study, we simply asked as concerned citizens for evidence of claims. As an alternative or even as a sub-study, we could pose as patients and ask for a recommendation for sample conditions. Indeed we could mobilise some real patients with real diseases. Are there any legal implications of this strategy?

It is important to be aware that non medicinal products are not aimed at patients – they are aimed at the worried well. Non-medicinal products do not treat diseases and if they make claims that imply they do, then there will be a breach of medicines legislation which falls to be enforced by the MHRA. However if the product is aimed at a patient group and the practice complained of doesn't fall within medicines legislation, then there is no reason why the CPRs would not apply. Therefore depending on the focus of the study, this may not have the desired impact.

There would need to be caution exercised in such study. HealthWatch would need to take specific legal advice on whether it could be exposing patients to 'risk' – otherwise it would be exposed to liability claims and conceivably health and safety issues would arise. Proper insurance cover is advisable.

Further, depending on the scale of the study, this may result in backlash from both the companies involved and Trading Standards. For instance, such a study has the potential to result in a disproportionate number of complaints against one product; this could divert resources from tackling another issue.

In instances where those with medical conditions are being enlisted for a study, there will be obvious medical and ethical consents to consider. Any such study would need to be conducted in the proper manner.

6. TSOs prioritise complaints by prevalence, ie if they have only had a few complaints they do not consider them worth pursuing. This is one reason for planning a much larger study involving many more complainants. However if this looks like an orchestrated campaign (which it is) does Trading Standards have the legal right to refuse to take action?

Trading Standards are under a duty to investigate but have a discretion to decline to prosecute any individual case (see above). As such, if a prosecution would be extremely costly and yet there had only been a handful of complaints and the offence was considered to be at the lower end of the scale, then there may be alternative means to resolve this that would be considered. For instance, even where Trading Standards have been referred a case by the ASA (as happened recently), they are not precluded from referring this back to the ASA.

Furthermore, the primary role of Trading Standards is to protect consumers. Traditionally this is exercised where a consumer or consumer group (as yet consumer groups do not have a civil right of action under the CPR) which has raised concerns whilst undertaking their everyday activity. It is open to organisations to raise issues with Trading Standards.

However, in relation to the CPR, there is again the issue of an 'average consumer' and this needs to be borne in mind as detailed above.

7. **TS argues that it has very limited resources and has to prioritise cases. False health claims are not considered important – financial and commercial violations have higher priority. The Regulations have clauses specifically aimed at health claims, and are the UK transposition of the EU Unfair Trading Directive. EU law requires that member states enable enforcement of EU Directives that are transposed into national law. We believe that technically the UK is in breach of EU law if it fails to provide for enforcement of the CPURs, and that complaints could be made to the EU Commission. Does such a course of action have merit, and is it feasible?**

There is a degree of flexibility in respect of enforcement. Both informal and formal enforcement methods can be used by Trading Standards as they consider appropriate. An informal method would be requesting that a business makes a change and then they do this. Formal methods would be prosecution.

Trading Standards consider a number of factors when deciding whether or not to take action, these include whether the prosecution would be in the public interest.

It is open to individuals or an interest group such as HealthWatch to bring private prosecutions. For instance the RSPCA regularly brings private prosecutions. Additionally, a decision not to prosecute can potentially be judicially reviewed. However, both of these mechanisms can be expensive and time consuming. Additionally a private prosecutor is at risk on costs if a prosecution is unsuccessful.

In terms of a complaint being made to the EU Commission, anyone can make a complaint against a Member State. This can be done for any measure or practice which appears to them to be incompatible with a principle or provision of EU law. In this instance, the basis for complaint would be that whilst the CPR transpose Directive 2005/29/EC in to domestic law, the CPR are not being enforced.

Article 11 of the Directive addresses enforcement. There is a degree of flexibility given to Member States as to how they enforce the Directive.

If there were a blanket policy that no action of any kind was to be taken to enforce false health claims as prohibited under the Directive because these are unimportant and due to financial and commercial violations, then this would clearly be in breach of the Directive. However, if actions were not being taken because it was considered that there were more appropriate and proportionate means to resolve this matter that would be justifiable.

The Directive also explicitly contains a caveat for actions to be taken in the public interest, whereby if Trading Standards can say that to pursue a prosecution is not in the public interest then this would be legitimate.

Furthermore, whilst the deadline for transposition of the Directive has passed, changes are being considered under the draft Consumer Protection from Unfair Trading (Amendment) Regulations 2013. The changes are intended in part to enable consumers to have a direct right of redress. The amendments are not particularly relevant to your considerations.

However, in considering the prospect of succeeding with a complaint to the EC it is relevant to consider that there has already been in depth analysis of the failings of the CPR.

In order to more fully advise on this, it would be necessary to consider in detail the material that you have, in particular the studies that you conducted.

8. **The gateway for Trading Standards is now the network of Citizens' Advice Bureaux. What effects do you anticipate from this change?**

It is now necessary for any person or consumer to contact the Citizens Advice consumer service in the first instance. The advisor will then make a decision as to whether a referral to Trading Standards is needed. There is a referral process in place and this affords for referrals that are considered to be urgent to be marked for rapid action.

Previously referrals were dealt with by Consumer Direct and when the service migrated to Citizens Advice consumer service some of those who had worked dealing with referrals at

Consumer Direct moved to Citizens Advice consumer service.

The main potential disadvantage of the service would be that because there are various layers to it and it may take some time for a complaint to be referred to Trading Standards. There may therefore be an unwillingness to continue to participate in the process after the initial complaint has been made.

In addition, the number to call to contact the Citizens Advice consumer service is an 0345 number. Whilst this is the same as calling a landline number, potentially this may cause confusion as to the charges. This should improve thought as 0345 numbers become more common. There are alternative methods of communication - these are textphone, an online enquiry form, as well as writing in.

Our general view as explained more fully above is that any complaint should be fully documented, referencing enforcement criteria and any material relevant to the decision to prosecute. Presenting a file in this way adds credibility and makes the enforcement decision easier for Trading Standards, but there is no guarantee of the outcome that HealthWatch prescribes.

Remember that any evidence presented to substantiate a complaint is capable of being disclosable in any subsequent proceedings. This is outside the scope of this advice.

- 9. Trading Standards has also been appointed as a back-stop for the Advertising Standards Authority, when traders persistently refuse to comply with the Code of Advertising Practice. Can you advise us on how this is expected to work? Two cases have already been referred to TS by the ASA under this arrangement, but we do not know yet under what legislation TS might act, if at all.**

Referrals

The two cases that have been referred are that of Electronic Healing and Fahrenheit60 Ltd. Fahrenheit60 supply a drink called Aspire, which alleges that it burns calories through a 'thermogenic' reaction. The referral is a consequence of failures to provide sufficient evidence to substantiate the claims. The ASA had placed the company on a list of non-compliant online advertisers. However, because the company continued to make problem claims, the case was referred to the Trading Standards.

In the case of Electronic Healing, they were investigated twice by the ASA in relation to claims made regarding 'Bob Beck Protocol' and 'Liquid Energy Drops'. The claims were found to be misleading and insufficient evidence could be found to support these claims. Again the company failed to desist with making problem claims.

It is not yet understood the legislation that Trading Standards are considering in these cases. Action could be pursued under the CPR. However, as Aspire is a drinks product, there may be The Nutrition and Health Claims (England) Regulations 2007 that they will consider. In an article from The Grocer last month, it stated that Fahrenheit60 are weighing up launching legal action against the ASA, as they consider that they have already taken action regarding the claims.

Legal Backstop

The role of the legal backstop for the ASA was previously occupied by the OFT. At the end of last year it was announced that Trading Standards would take over this role.

As such, non-broadcast advertisers who persistently break the rules on misleading advertising can be referred to Trading Standards. Trading Standards will then consider statutory action. This will include warnings but can also be civil enforcement orders or criminal prosecution.

It will be the Trading Standards team in Camden who will deal with these referrals.

However, should they feel unable to take action then the case can be referred to the National Tactical Tasking and Coordination Group.

There are specific cases handling procedures for matters in the UK. The grounds for referral

from the ASA to the London Borough of Camden state that most cases will fall within the remit of the ASA. It is understood that as with referrals from the ASA to the OFT it will generally be the most serious cases, especially where they are repeat-offenders.

10. There have recently been a few prosecutions by TS for misleading health claims, for example the 'live blood analysis' offered by Errol Denton (http://rationalwiki.org/wiki/Errol_Denton). Do you have any comments on the legal basis of this and similar prosecutions? Were they made under the Regulations?

Errol Denton

Mr Denton was prosecuted due to the publication of advertisements claiming to treat cancer. This prosecution was under The Cancer Act 1939, rather than the CPR. Mr Denton was prosecuted for nine breaches of s4 of the Cancer Act.

Mr Denton was fined £9,000 and ordered to pay costs of £10,000.

Arcturus Clinic

In 2012 a conference exploring alternative treatments for cancer was investigated by Trading Standards. The conference was originally scheduled to take place in the Civic Hall in Totnes but permission was withdrawn. The meeting was held in an alternative private location.

It seems that one of the primary issues was that oncologist Tullio Simoncini, who has been struck off, was due to attend the conference. He is alleged to have made claims about baking soda being used as a treatment for cancer.

Trading Standards investigated and considered that the organiser of the event and manager of Arcturus Clinic, Dr Stephen Hopwood had breached the Cancer Act 1939 and said that the clinic would be monitored. However, no formal action was taken.

Next Steps

In relation to pursuing this matter further, there are some potential next steps that we could consider pursuing for you:

- Freedom of Information Request – in respect of the guidance referred to by the Trading Standards we could request this. In addition, we could request details of any prosecutions under the CPR for misleading health claims.
- Review of potential strength of any complaint to the EC – this would involve considering the material gathered in the report in detail to evaluate the strength of any claim.

DWF LLP

23 June 2014

18.3.2 Follow-up advice (pre-study)

Thank you for your email of 19th August raising the following observation:

“Schedule 1 Para 17 of the CPRs, which states that "Falsely claiming that a product is able to cure illnesses, dysfunction or malformations" is always unlawful. It seems to me that any such claim would be a medicinal one, and thus subject to the Medicines Act. You have made it clear that the CPRs are for non-medicinal claims, ie the 'worried well'. Therefore, if we do find a trader who falsely claims to cure a disease, and complain to Trading Standards, the latter may well cite the primary legislation principle and bounce it off to the MHRA”.

You have then asked “If that's the case, I don't see how Schedule 1 Para 17 of the CPRs can ever apply. Do you agree?”

Your observation is correct. The prohibition against making medicinal claims such as “Falsely claiming that a product is able to cure illnesses, dysfunction or malformations” is always unlawful and prohibited under several pieces of legislation (for example medicines and foods as well as the CPRs). In relation to medicines, most are clearly identifiable as such and are subject to EC marketing authorisation procedures. However, there are some products where it is not so easy to distinguish a medicine from, for example, cosmetics or food supplements. These are known as borderline products.

A product which is for use only as a toilet preparation, disinfectant, food or beverage is not normally regarded as a medicinal product, and, therefore, does not require a marketing authorisation before being sold in the UK. Similarly, dietary supplements, containing such familiar substances as vitamins, amino acids or minerals, are generally subject to food safety and food labelling legislation rather than medicines control.

However, should any of the above contain a pharmacologically active substance or make medicinal claims (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal). For example, a toothpaste would generally be considered as a cosmetic, but if it is marketed with claims to treat or prevent 'sensitive' teeth or it contains an active ingredient known to have such an effect then it would fall within the definition of a medicinal product and be subject to medicines control.

The EU Directive (2001/83) governing medicines makes it clear under Article 2(2) that where there is overlapping legislation medicines legislation will take precedence. Article 2(2) states that :

“In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a ‘medicinal product’ and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.”

This means that medicines legislation will take precedence over other legislation such as cosmetic and food legislation as well as the CPRs. Therefore it is likely (but not always the case) that Trading Standards will refer such cases to the MHRA. This is not necessarily a bad thing as the MHRA has additional statutory powers to issue provisional determinations as to whether a product is medical. This is done by way of a determination which are usually complied with. If not the perpetrator can be prosecuted.

However it is not correct to say that all cases will be dealt with by MHRA, Trading Standards may decide to prosecute the matter themselves particularly when it is only one issue under the CPRs, General Product Safety Regulations 2005 or other legislation. For example in the case of Errol Denton a prosecution under the Cancer Act.

Therefore in answer to your question. There is a large degree of overlap between the provisions of the CPRs and other legislation. Usually product specific legislation will take precedence over the CPRs and in all cases medicines legislation takes precedence over other product specific legislation where medicinal claims are made. However regulators have a degree of latitude and discretion about which of them will take a case and under which legislation they will prosecute under. For example the Arturus Clinic. As such there will be occasions when the provisions of schedule 1 para 17 of the CPRs are used but it will usually be in conjunction with other breaches and the Trading Standards are permitted a degree of discretion in determining in which cases its used.

Email received from DWP LLP 2nd September 2014

18.3.3 Post-study Advice

1. Question

1.1 We have been asked to advise Healthwatch in relation to the enforcement of consumer protection legislation.

1.2 Healthwatch's query arises following a study into enforcement during which a variation in approach to enforcement between different regulators was identified. Healthwatch has provided us with a response (the 'Response') from Trading Standards to illustrate the issue¹:

"www.asyra.co.uk and www.halcyonbracelets.com are both making specific claims about specific products. Trading Standards are not best placed to determine the accuracy or otherwise of these claims and have no powers to demand that businesses prove the accuracy of claims to us without reasonable grounds to suspect that an offence has been committed. We would need to prove that a claim is false or misleading beyond reasonable doubt before we could consider taking any formal action. However, the Advertising Standards Authority (ASA) now has marketing on companies' own websites, as well as external advertising, within their remit. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. Consequently you may wish to refer your concerns about any specific claims on these websites to the ASA."

1.3 Healthwatch is already familiar with the roles of Trading Standards and the ASA, but would like to understand whether the Response is a true reflection of the law and in particular, whether it is correct that Trading Standards is obliged to prove a claim is false, while the Advertising Standards Authority ('ASA') is not?

1.4 We will first look in more detail at their respective remits as advertising regulators before moving on to consider whether there is a difference in the way they investigate and prove complaints and exercise enforcement powers, particularly in the context of the Consumer Protection from Unfair Trading Regulations 2008 ('CPUT').

1.5 For ease of reference, we summarise the key differences at Appendix 1.

2. Regulatory Status of Trading Standards and the ASA

2.1 Trading Standards has a duty to enforce CPUT². This is not absolute duty as Trading Standards authorities are empowered to determine how to comply with its duty of enforcement do so by

having “regard to the desirability of encouraging control of unfair commercial practices by such established means as it considers appropriate having regard to all the circumstances of the particular case”³. This means Trading Standards may decide how it enforces the CPUT on a case by case basis.

2.2 It is a criminal offence to breach CPUT and Trading Standards technically have the power to prosecute each case in the criminal courts if it decides to do so.

2.3 However, CPUT also allows Trading Standards to use alternative 'established means' of regulation (including self-regulation) where appropriate to control unfair commercial practices. The ASA are considered the 'established means' for controlling unfair advertising.

2.4 Trading Standards have statutory powers and functions than the ASA⁴ and as such, have methods of enforcement and sanctions which are simply not available to the ASA, including informal warnings, warning letters, statutory notices, simple cautions and prosecution in the criminal courts.

2.5 The ASA is not empowered to take any such 'legal' actions, but it does some powers that can have adverse implications for advertisers, including the power to publish their rulings on the ASA website⁵.

2.6 As a public body with enforcement powers, Trading Standards must exercise its regulatory function in compliance with certain public standards and codes of enforcement.⁶ As a self-regulatory organisation, however, the ASA is not bound by the same enforcement standards and codes, albeit it does operate a 'Commitment to good regulation', which is purportedly modelled on the Regulator's Code.

2.7 Trading Standards must act in accordance with its statutory powers as well as with regulators' codes. Two key points arise from the standards and codes of enforcement that apply to Trading Standards in the context of the Response:

1. In order to determine compliance the CPUTs gives Trading Standards the powers to make test purchases⁷ and, if there is a reasonable cause for suspecting an offence has been committed require documents, seize and detain goods⁸ etc. There is an important distinction between the power in Regulation 20 and those in Regulation 21. In order to rely on the powers provided under Regulation 21 the Trading Standards officer must have reasonable grounds for suspecting an offence has been committed. This must be determined as an objective question on the basis of the matters known to him at the time eg a test purchase or a complaint.

2. Even if a Trading Standards Officer has a reasonable ground to suspect an offence is committed he must also have regard to other issues such as proportionality and the guidelines on criteria for prosecutions⁹ and only bring a prosecution (or formal enforcement) if:

(i) there is a realistic prospect of a conviction (the 'evidential test'); and

(ii) it would be in the public interest¹⁰ (the 'public interest test').

2.8 It is in contemplating the evidential test that the question of whether it will be possible to prove that a claim is false or misleading will arise. In order to assess this, Trading Standards would need to investigate and gather evidence, which would likely involve speaking to the advertiser and potentially obtaining expert evidence of their own. Even if Trading Standards find the claims to be misleading, they may not consider the breaches serious enough to meet the public interest test for prosecution or formal enforcement.¹¹

2.9 The ASA also have prioritisation principles¹² to determine what action they should take (which can include resolving complaints informally so that a ruling is not published). However, in our experience, the ASA is far more likely to decide that a formal investigation is proportionate,

meaning that the case will be presented to the ASA Council¹³ to make a final ruling. This is because regulating advertising is their *raison d'être*, whereas formal action for an advertising breach would not typically be consistent with Trading Standard's duty to act proportionately or indeed meet the public interest test.

2.10 The CAP Codes do require advertisers to hold appropriate evidence to support the claims made in their adverts and it is this evidence that the ASA will assess when deciding what action to take. In this sense, the onus is on advertisers to prove the truth of their claims. As with Trading Standards, the investigation process will involve obtaining representations from the advertiser and potentially obtaining an independent expert opinion where evidence is of a highly technical or specialised nature. If the ASA consider formal action is appropriate, the evidence is then put before the ASA Council for a final ruling.

2.11 In terms of who has the burden of proving a breach, if Trading Standards were to prosecute an alleged breach in the criminal courts, the burden of proving that the advertiser is guilty of making misleading claims will fall on Trading Standards, who must prove the offence beyond reasonable doubt. As such, the court must be certain of guilt before they can convict.

2.12 By contrast, there is no burden or standard of proof that must be met by the ASA when referring matters to the ASA Council. Indeed, the onus is on the advertiser to satisfy the ASA that the claims are substantiated in order to try to avoid referral to the ASA Council. The ASA Council make the final decision on whether adverts breach the CAP Codes.

3. Is it correct that Trading Standards is obliged to prove a claim is false, while the ASA is not?

3.1 Looking at the text of the Response we can see why Healthwatch has questioned the response as it is confusing. However if its distilled down it is generally correct:

1. Trading Standards has no powers to demand that businesses prove the accuracy of claims without reasonable grounds to suspect that an offence has been committed. This is correct. Trading Standards are only empowered to use their investigatory powers when they have grounds to suspect an offence has occurred. However such grounds could be based on a test purchase or a complaint. In this case they had a complaint, which is usually sufficient to meet the test of reasonable cause to suspect an offence has been committed and start an investigation. However we would emphasise that when a complaint is received Trading Standards must be satisfied that the complaint is sufficient ie not malicious and indicates an issue has occurred. Even if the officer is satisfied Trading Standards also have the discretion to determine how to comply with Regulation 19 (4) which includes an ability to refer the matter to the ASA.

2. Trading Standards need to prove that a claim is false or misleading beyond reasonable doubt before taking any formal action. It is correct that they must have regard to whether the evidence satisfies the evidential test before deciding whether to proceed with a prosecution (i.e. whether there is a realistic prospect of a conviction). If they decide that this test is met and that prosecution is in the public interest, then (and only then) is the burden on them to prove to the court 'beyond reasonable doubt' that the offending advertiser is guilty of the alleged offence.

3. If a complaint is made to the ASA about a specific matter then the onus would be on the business that the complaint is made against to be able to prove the truth of it. The nature of the ASA complaints procedure does mean that the advertiser needs to provide evidence to satisfy the ASA that the claim in question can be substantiated. Unlike Trading Standards the ASA does not have a standard of proof to reach.

3.2 In conclusion, Trading Standards Authorities do have the discretion to determine the 'established means' for controlling unfair advertising should be the ASA. This can lead to a difference in approach across Trading Standards across the country.

Footnotes

1. Trading Standards were asked to consider breaches of the Consumer Protection from Unfair Trading Regulations 2008
2. Regulation 19(1) of the CPUT
3. Regulation 19(4) CPUT
4. Trading Standards being the enforcement arm of the local authority with regulatory functions specified by statute, whereas the ASA is a voluntary self-regulatory organisation (funded by industry levies and established by the Committee of Advertising ('CAP') to adjudicate and enforce the voluntary UK Codes of Broadcast and non-broadcast Advertising ('CAP Codes')) carrying out a public function.
5. As well as some powers to restrict advertising, including pre-vetting, ad alerts, withdrawal of trading privileges and online sanctions, i.e. internet search websites can be asked to remove a marketer's paid-for search advertisements. These are powerful deterrents due to the potential for negative publicity.
6. I.e. the Regulator's Code, Local Authority Enforcement Policies, Code for Crown Prosecutors
7. Regulation 20 CPUT
8. Regulation 21 CPUT
9. Code for Crown Prosecutors
10. Typically, the more serious the offence, the more likely a prosecution will be needed in the public interest, but other factors include that the defendant has failed to act on advice, guidance or a warning which had been given on a previous occasion
11. Prosecution guidelines indicate that in most cases, the decision whether to prosecute should only be taken after an investigation has been completed and all available evidence reviewed. However, where it is clear, prior to the collection and consideration of all likely evidence, that the public interest does not require a prosecution, the case should not proceed further.
12. Taking into account harm or detriment; the risk of taking action versus inaction; the likely impact of intervention; and what resource would be proportionate.
13. made up of 13 people, with two-thirds being independent of the advertising industry

Appendix 1 of Post-Study Legal Advice

	Trading Standards	ASA
Regulatory Status	Public Body, enforcement arm of the local authority with regulatory functions specified by statute.	Voluntary self-regulatory organisation (funded by industry levies) carrying out a public function
Source of regulation to be enforced	CPUT	CAP Codes (which refer to CPUT)
Sanctions	Variety of enforcement actions, including warning letters, statutory notices, simple cautions and prosecution in the criminal courts	Publishing informally resolved cases and formal rulings, pre-vetting, ad alerts, withdrawal of trading privileges and online sanctions, i.e. internet search websites can be asked to remove a marketer's paid-for search advertisements.
Enforcement Codes	The Regulator's Code, Local Authority Enforcement Policies, Code for Crown Prosecutors	ASA/CAP Commitment to good regulation
Relevant duties under Enforcement Codes	To act proportionately in relation to investigations and enforcement action; To have regard to the criteria for prosecutions and only bring if: (i) there is a realistic prospect of a conviction; <u>and</u> (ii) prosecution would be in the public interest	Prioritisation principles
Investigation	Involves gathering evidence, including obtaining representations from the advertiser and expert opinion where necessary	Involves gathering evidence, including obtaining representations from the advertiser and expert opinion where necessary
Burden and Standard of Proof	When prosecuting in court must prove offence beyond reasonable doubt. Otherwise, no formal standard of proof for alternative enforcement actions; subject to enforcement code.	Onus is on the advertiser to substantiate claims to avoid formal action. No formal standard of proof

Further clarification of legal advice

Responses from legal advise are italicised.

Thank you for your email. In your last email you asked a very specific question about whether the TS response was correct. Although not exactly correct, and not explained terribly well, the TSOs explanation was in general correct. The questions set out below are broader and highlight why the matter isn't straight forward. I have answered the questions below which I hope clarifies matters.

2.3 Trading Standards (TS) is the legal backstop to the ASA. Specifically this function is provided

by Camden Council TS office. It seems illogical therefore for TS to revert to the ASA as 'established means' of enforcement. How is this not circular? In this study we deliberately eliminated the ASA step so as to focus on TS powers, which should in any case be applied to the ASA's non-compliant advertisers.

The law is circular and gives Trading Standards a discretion on a case by case basis. Can you not make the point that in each case regardless of the circumstances of the case TS refused to apply their powers and therefore are abdicating their duty to enforce the CPUT in all health claim cases?

2.8 The preceding paragraphs set out how TS powers differ from, and exceed, those of the ASA. But you say here that the evidential threshold is set by TS very differently. The ASA simply asks for evidence, assesses the evidence for robustness, and judges accordingly. This is the scientific method. The ASA does engage experts to assess the evidence (I have acted as such an expert on several occasions). TS you say takes a more cautious approach, by "obtaining expert evidence of their own". It seems to me therefore that an advertiser adjudged by the ASA as non-compliant, because they could not provide robust evidence, would be assessed to a different and less rigorous standard by TS. I wonder therefore how TS can ever act effectively as a legal backstop for the ASA with regard to the CPUT (which we call the CPRs). Does this explain why there are currently 53 cases on the ASA's non-compliers list and only 34 have been referred to TS? Of the latter, six were referred over one year ago, with no indication of any action being taken by TS. When the CPUT regulations came into effect it was widely expected that the onus of evidence would pass to the trader. Were we wrong?

I think this is where the misunderstanding occurs. The legal standards that TS has to assess compliance with are higher than those under which the ASA operate. It is generally accepted to be easier for the ASA to adjudicate than for TS to bring a case to court. TS have to meet a far higher burden of proof than the ASA in order to bring a case successfully. The ASA have no legal threshold to meet. It is of course subject to Judicial review so cannot act unreasonably. This is one of the main reasons why ASA deal with the majority of cases. The other issue is money. TS have to deal with a wide range of issues not just the CPUTs and have to allocate budgets accordingly. Budget is probably the largest driver is the fact that TS now have very limited budgets and therefore this is a quicker, cheaper and more certain way to address issues.

The CPUTs did make it easier in some ways for TS to bring certain cases as it defined, prohibited, aggressive and blacklist activities. However TS still has to collate the evidence and meet the required standard of prove. The ease (or otherwise) of this will depend on the case. However it did not change the onus of prove except for civil actions under the Enterprise Act. Additionally, the non-compliance list only applies digital advertisers and not other media so it only relates to part of the market and is not therefore totally representative picture.

In your email of 22nd September you said "As you suspect this response is not quite right", regarding the TS response we received. This response said "We would need to prove that a claim is false or misleading beyond reasonable doubt....". Are you now saying that this response from TS is in fact correct? We commissioned the present advice principally in order to find out in what way this was "not quite right".

The TSO response is not quite right as in order to bring a prosecution under the CPUTS the TS do not need to prove a claim is misleading or false beyond reasonable doubt but rather need to be satisfied that there is a reasonable prospect of conviction, ie of showing these things. They also failed to explain to you that they have the discretion to refer the matter to the ASA etc. Therefore my advice has not changed.

We received other legal advice, before the present study, which said that health claims made which were not based on science were extraordinary claims. Such claims would be for the claimant to

substantiate, not for TS to disprove. More mundane claims, such as serving short measures of beer in a pub but claiming they were not short, are not extraordinary and are easy for TS to test and disprove. Has this principle been superseded, or was it always wrong? The CPUT regs do say that if a case comes to court, it will at that stage be for the advertiser to substantiate their claims (see 2.11. below). So why does TS not apply that standard at the outset?

The laws on Health claims for foods have changed but the principles remain generally correct.

Health claims are now regulated by Regulation 1924/2006. This creates an EU register of authorised claims and non-authorised claims. The only exception is claims for foods with on hold claims such as claims for herbal ingredients which fall to be regulated under national laws. Therefore if the question is whether the health claims being used is authorised then this is fairly straight forward for TS to enforce. They look up the EU register and compare the claims. It becomes more difficult if a claim is authorised but slightly different wording has been used by the advertiser or its been presented out of context. In such a case it may be more complex for TS to bring a case. Another example of a more complex case for health claims is foods with herbal ingredients- the advertiser would still need to demonstrate that they had evidence to substantiate their claim. If they did provide evidence TS would evaluate it and determine its robustness (often with the help of scientific experts like yourself). This would allow them to determine if there was a realistic prospect of conviction if they took a prosecution.

Some non-health claim types claims are easier to bring than others. For example if a product is advertised as costing £4.99 but in fact is sold for £14.99 the TSO can bring a case more easily ie they need a copy of the advert and a copy of a receipt.

In either case you would expect the prosecution to show why they believe the claim to be misleading.

2.9 In addition to reversing the evidential onus, TS also has discretion to set a lower priority for CPUT complaints. I fully accept that they have a broader remit, but again it seems that such cases will always be given lower priority by TS than they are by the ASA, simply because within TS there is more competition for resource. While that is a reality, I can't see how TS can be fully effective as the ASA legal backstop.

This would appear to be a strong point particularly if your study shows that TS have in place a blanket policy of not dealing with health claims.

2.11 Section 27 of the The Consumer Protection from Unfair Trading Regulations 2008 states (inter alia):

"(2) For the purposes of considering the application the court may require the person named in the application to provide evidence as to the accuracy of any factual claim made as part of a commercial practice of that person if, taking into account the legitimate interests of that person and any other party to the proceedings, it appears appropriate in the circumstances.

(3) If, having been required under subsection (2) to provide evidence as to the accuracy of a factual claim, a person—

(a) fails to provide such evidence, or

(b) provides evidence as to the accuracy of the factual claim that the court considers inadequate, the court may consider that the factual claim is inaccurate.

In what way does this not say that the claimant bears the onus of substantiation?

This applies to legal proceedings brought under the Enterprise Act 2002. It relates to civil proceedings involving Enforcement Notices not prosecutions.

We embarked on this study on the basis of your firm's original advice. We built in a sequence of communications with TS which included requests to advertisers for evidence, detailed complaints and follow-up letters, cease and desist letters, and regular follow-up once we knew which TS office was involved. All of these contained specific wording as advised by yourselves. The whole process was designed to elevate the priority level which TS might apply. It was so cumbersome that many team members dropped out. Yet despite this laborious process you seem to be saying that TS still has the discretion to ignore all complaints.

I have not said that TS have a discretion to ignore all complaints. They have the discretion to look at each case on its own merits. If they are ignoring all complaints then this may indicate a blanket policy decision which could be challengeable by Judicial Review. This would depend on the evidence to support such an application.

The outcome of the study is that there is very little evidence that TS enforces the CPUT regs with regard to health claims, and if this really is the legal position I can see why.

Also you need to bear in mind that the primary criminal offence for making an unauthorised nutrition or health claim is under the Nutrition and Health Claims (England) Regulations.

18.4 `Cease and Desist' Letter

The following template letter was provided to investigators:

Dear [name]

I write as a concerned citizen, regarding your product/service (name of product/service]. I viewed your website at [URL] on [date] and noted that the following claim(s) is/are being made:

[copy text from website here]

I previously asked you, specifically on [date], to provide robust evidence to support this claim, and you failed to provide such evidence. Therefore the claim is misleading, and is not permitted under the Consumer Protection from Unfair Trading Regulations 2008. It may also violate other consumer legislation.

Demand is hereby made that [company name] and any and all affiliates of your company, immediately stop using any and all advertisements and websites that contain false and/or misleading representations of fact regarding the effects of [product] on [condition]. Demand is also made that [company name] publicly retract the false and/or misleading representations of fact in an appropriate manner, namely by a statement on your website. Failure to immediately cease and desist from false and/or misleading representations of fact, and failure to retract the statements set out above, will result in a formal complaint to the regulatory authorities, seeking enforcement action.

I recommend that you forward this letter to your legal advisers. I look forward to receiving your response by [10 days from now].

Yours etc

18.5 Letter to Citizens Advice and/or Trading Standards

The following template letter was provided to investigators:

Dear Sirs

Re: [TS reference number and name of trader]

Many thanks for acknowledging this complaint. Please note that I have no commercial interest in the product/service concerned, and am acting entirely as a concerned citizen.

I have asked the trader for evidence to support the claims being made, and the trader *did not respond/provided inadequate documents/responded but did not provide any evidence (delete as appropriate, or use your own wording)*. I note that as at [date] the claims were still being made.

I am deeply concerned that these claims could have the following effects:

1. An average consumer, not familiar with the scientific and medical background to their situation, could make an inappropriate decision regarding their health. They could be misled into spending money on a product/service from which they will derive no benefit.
2. A vulnerable person, with what appears to be a benign physical complaint but which could actually signal something more serious, could be attracted away from seeking professional medical help. This has been found on many occasions to be a serious problem, resulting sometimes in death.

The claims made are not only misleading, they are extraordinary. There is no known scientific basis for the claims, and no scientific tests have verified them. This places the burden of proof on the trader making the claims, and when challenged no such proof has been provided.

I have asked the trader to cease making the misleading claims, without result. My letter requesting this is attached. As of [date] the claims were still being made at [URL]. I believe that these claims are unlawful under the Consumer Protection from Unfair Trading Regulations 2008, and may also be caught by other consumer legislation. Because of the serious nature of the claims, and the persistent nature of the trader's non-compliance, I am asking Trading Standards to prioritise this case and to engage with the trader at the earliest opportunity.

I am at your disposal to assist in any way I can to further this case. In particular I am conscious that the trader continues to do business on the basis of these misleading claims, and I look forward to hearing from you again very soon with your proposed course of action.

Yours etc

19 Raw Data

The original Google Sheets data were exported in Open Document Spreadsheet format (ODS). A file containing all data is archived by HealthWatch, and is available on request.

20 References

- 1 Rose LB, Posadzki P, Ernst E. Spurious Claims for Health-care Products: An Experimental Approach to Evaluating Current UK Legislation and its Implementation. *Medico-Legal Journal* (2012) Vol. 80 Part 1, 13–18.
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- 6 Chartered Trading Standards Institute Workforce Survey 2016.