

# Effectively meeting a legal challenge

Last year there seemed to be an obsession with litigation – with more companies targeted for compensation than ever before. Offered here are some ideas for fights ahead. Patience and a sense of humour are essential in order to retain sanity when a claim arises.

## Litigation and related issues

The growth of opportunistic treasure seekers has led to a large increase in accident-claim solicitors fighting on behalf of clients seeking compensation for irritation resulting from using a cosmetic or skin care product. It is hard to remember a time when so much effort has been spent fighting off such claims which are often ill-founded and opportunistic.

Companies need to have a strategy and action plan in place for such events, because it is likely that they will have to pull a team together at a moment's notice with a leader who is given responsibility for ensuring that the matter is dealt with competently and quickly. The aim of this article is to provide a checklist of ideas and procedures to ensure success in the case of a challenge. It is also worth noting that an industry expert from outside your team or company can often discourage a case from going to court.

The scenario often starts with a consumer demanding compensation and claiming that he or she has skin damage resembling a third degree burn and that he or she has been to a doctor who says that medical science is unable to help despite having prescribed vast amounts of corticosteroids. Pictures are often available, but only through solicitors. On no account admit any liability at this stage. By all means express concern that this event should have occurred, but do this without prejudice. Refund the cost of the product and the postage. A useful paragraph in these circumstances is to confirm that your product completely



satisfies the appropriate regulations, such as the UK's Cosmetic Products (Safety) Regulations 2004 as amended, and that there has been no complaint about this product in its history of sale. Always reply to a consumer and always fully investigate every complaint. Naturally, if there has been a history of complaints then as a responsible company you should have fully investigated and dealt with every single one and even recalled a suspect product.

In the event that a customer writes again, then consider the option of offering a patch test with a dermatologist to find out what raw material the individual may be allergic to or may find irritating. Explain that on very rare occasions this can occur despite every duty of care and that is why every ingredient is listed on the pack to enable consumers to identify those which may not agree with their skin type.

If this helpful attention fails, then the consumer may go to a specialist solicitor or, in the UK, to the Trading Standards Office. In some cases, the legal

representative may be aggressive and not at all understanding of the law and the regulations that are followed by the industry. The tenant to remember is that "we are all innocent until proved guilty".

The second major point to remember is that you have all the time in the world and are only required to acknowledge the receipt of their letter within a week or so. In the UK, the Trading Standards Officer is normally understanding and well used to this type of complaint, which rarely makes it to court if you are properly prepared.

The following action points should be undertaken by any company faced with a claim:

- Look back in the files to see whether this customer wrote to your company initially and retrieve your reply/replies, which should have been dealt with as described above. Make copies of this correspondence and the solicitor's letter and start a new file.
- Contact your insurers and provide them with copies of the correspondence in the new file.

## Information pack

Procedures followed in the UK have similar counterparts elsewhere and should be widely noted. In a case being dealt with by the UK's Trading Standards Office, the company concerned must have a full PIP (Product Information Pack) available in two to three working days. The faster the information is supplied, the more respect the Trading Standards Office will have for you and the less worried it will be about the competency of your business. The data should include the following:

- Product description and codes or formulation code.
- Product formula including percentages, INCI names, trade names and suppliers.
- Raw material ingredient specifications and technical data sheets.

- Manufacturing procedure summary or single page flow chart.
- Summary GMP statement (a statement on company headed paper declaring ISO standards and/or GMP compliance).
- Product safety assessment statement.
- Undesirable health effects summary.
- Claim substantiation summary with references. This is proof that pack claims are able to be substantiated.
- Stability summary, with reference to methods. This is usually a spreadsheet showing the stability at ambient, 30°C, 40°C, freeze-thaw etc.
- Specification; i.e. viscosity, pH and other test data listed.
- Microbiological challenge test records for products that contain water.
- Proposed pack copy or artwork for each carton and label.
- It is useful to include a picture of the final product in the PIP.
- Perfumes and flavours should have IFRA and/or RIFM compliance statements from the perfume house.
- Perfumes should have the 26 potential allergens content list from the perfume house.
- Additional data may include user trials, instrumental data, analytical data and other facts to support the claims and/or safety of the product.

Trading Standards will prosecute if this PIP (and all of its components) is not available because it is mandatory in law. If your company can demonstrate that it is in control of its legal requirements, has shown all fair and reasonable duty of care to its consumers, has not been negligent in its surveillance and has monitored its product through its entire history (including all complaints) then they are not likely to prosecute.

### Ridiculous assertions

Sometimes a solicitor may try and prove all manner of ridiculous assertions, such as your company is using forbidden drug materials. There are some materials that are not allowed internally in pharmaceuticals but are perfectly legal in topical products.

To follow are some extracts from a letter to one of these legal accusers. Its purpose is to show them that the defendant's knowledge of the law is greater than that of the accuser.

- "Kava Kava (*Piper methysticum*), although banned in dietary supplements, is not banned for use in topical products and appears in Commission Directive 2006/257/EC amending Decision 96/335/EC establishing an inventory and a



*A consumer's claim for compensation needs precise responses.*

common nomenclature of ingredients employed in cosmetic products dated 9<sup>th</sup> February 2006. We draw your attention to the exact ruling MLX 286 by the (then) Medicines Control Agency in 2002.

- "Thiomersal is legally permitted in eye make-up and eye make-up remover up to a maximum of 0.007% calculated as mercury. When mixed with other authorised mercury compounds the total mercury concentration must not exceed 0.007%. Such products are required to be labelled "Contains thiomersal".
- "Likewise there are lightening products apart from hydroquinone (such as kojic acid and arbutin) that are perfectly legal in topical skin care products.
- "Mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate [Methylchloroisothiazolinone and Methylisothiazolinone] is a well known preservative (trade name Kathon CG) used at 0.0015% of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2H)-one to 2-methylisothiazol-3(2H)-one. This blend is a permitted preservative in Annex VI Part 1 of the regulations and in no way related to Thiazolidinediones (a diabetic drug)."

A phrase guaranteed to have maximum impact is: "We are very particular when it comes to the law governing cosmetics and the need for accuracy should not be obscured or threatened by an ignorance of that law".

Contest every statement made against your company and have evidence to

support every statement you make. Challenge every nonsensical statement with authority, because many solicitors know a lot less than you do on the subject of cosmetics and are trying to intimidate with legalistic jargon.

Eventually there will come a time when the correspondence cycle is complete. Often dozens of letters will have been exchanged between your insurers, the claimant's legal team and whoever else has been drawn into the loop. Many hours will have been wasted but it is a lucrative time for those who are being paid for these hours.

After more than a year it is possible that the barristers will be called in, which means that the legal costs escalate from around £50 per hour for each player to around £500-£1,000 per hour for the new teamsters. If your company does not have insurance, the situation is particularly serious. Remember that diligence and the willingness to fight every argument leads to many cases failing because they appear too hard to win. If your company seems to have covered all the bases and is eager to fight, then most cases will evaporate.

In all the time that this round of legal banter has been in progress, you should be assembling a file of information that puts your product beyond all reasonable doubt. You should commission a repeat insult patch test, conduct user trials, and seek dermatological proof that your product is as harmless as you knew it was. An eager defendant will have done a full battery of animal alternative tests in preparation for a court appearance.

During this time two files should be available. One is an electronic version on CD ROM which is all perfectly indexed with all the documents linked through to a hyperlinked spreadsheet (for the defence team), with the really useful documents highlighted. The other version is the paper alternative in at least half a dozen lever arch files, which is for the plaintiff's team. Most legal teams are exceptionally grateful for this seemingly endless supply of paperwork and are always thrilled to receive a crate full of information.

### The legal portfolio of evidence

Every document you can lay your hands on should be placed in these files and all the documents should be labelled in a way that is fully understood by you and your defence team. The files should contain:

- The full Product Information Pack now extensively supplemented as described above.

- The MSDS for every single raw material used in the product.
- The technical data sheet for each and every raw material.
- The folklore and ethnobotany of a natural product. This is a really fascinating topic that can run into vast numbers of pages and that are essential evidence in proving the safety of an individual raw material.
- Toxicity files (where available) should also be included for each ingredient. Regrettably these can also tend to be quite verbose and lengthy.
- Copies of the inspection reports for every single raw material at the time of production are essential but dull reading. Lots taken before and after the production date are always helpful for comparison to show a normal compliance and that there was nothing out of the ordinary. Regrettably, this puts an additional burden on the volume of paper supplied.
- Certificates of conformance for every raw material used are absolutely vital.
- The batch sheet for the product under dispute and all related documents such as the demineralised water conformance report for that month.
- The qualifications and personnel reports for the staff involved in the production of the batch including details of all relevant training received.
- The quality control sheet for the proof of compliance to the product's specification and the full protocol for the use of the equipment to make those measurements accurately (the standard operating procedure).
- Helpful information such as published papers on active ingredients.
- A survey of information from the internet. This should be a part of the package and show a history of safe and common usage for the raw materials.
- A copy of the Cosmetic Regulations and all its Appendices.
- The PAO (Product After Opening) explanation document.
- The Challenge Test protocol.
- The MHRA Guidance Note 8. This is excellent and will provide a good read for the attacking solicitor and his team.
- HACCP (Hazard and Critical Control Points) analysis. This will also have been conducted for this product and should be included in the data.

This information should be sectioned into reasonable categories which you and your defence team can easily locate any

document, but which the plaintiff's team may consider to be a paper maze of unfathomable complexity. Your barrister should have the headlines of your defence well laid out in two to three concise pages.

### The winning stroke

The following should be kept in one last file:

- Instrumental data.
- Clinical data.
- Statements of opinion and other last minute defence strategies.

This last file can be supplied on the morning of the trial, or on the day before, as late evidence and is best supplied direct to the plaintiff's solicitor by courier. The first morning of most trials is spent seeing what evidence has been lost or misplaced. The chances of losing are quite slim if you have all the data and if the case has been prepared well. The last consolation is to remember that this vast data can be assembled very easily and will tie up a legal brain for many hundreds of hours, which is why some cases can last for four years or even more.

It is only by making this industry an unattractive target that we will discourage people from targeting it in the courts in order to make a profitable living. **PC**