

Health Watch Newsletter

Enhancing informed choice through reliable information

Newsletter 12, Summer 1993

Health companies avoiding law to claim wondercures

Claims that alternative health products can cure or prevent diseases are being made by some companies that have found ways of avoiding the Medicines Act. The companies are exploiting legal loopholes or weaknesses in the regulatory bodies to make these medicinal claims. The Medicines Act is meant to protect the public from unsubstantiated medicinal claims, but companies are getting their messages across by avoiding the most strictly controlled methods of advertising.

These findings come amidst calls from both inside and outside the £227 million health supplement industry for stronger means of taking action against companies who make forbidden claims. Some people say they they are frustrated that the making of UK legislation has been frozen while the EC discusses a directive on nutritional supplements. This directive is moving so slowly that it has been estimated that it could be three years before any legislation comes into force in the UK.

Claims that a product can cure or prevent a disease must not be made unless it has been granted a product licence under the 1968 Medicines Act. This requires rigorous evidence for the efficacy, safety and quality of the medicine.

Mail shots

Methods for getting round these strict rules are described in this issue of HealthWatch. They include mailshots in which people are sent books and press cuttings that appear to have been written independently of the manufacturer. They include freephone information lines on which enquirers are told that products can cure diseases and banish pain. They include leaflets, strewn about health shops and pharmacies, that make claims that cannot be made on the product's packaging.

For some products, a medicinal claim is suggested by the name. Some firms

are bombarding their customers with claims by post. Others are putting their medicinal claims into mail order catalogues that are then advertised in magazines and newspapers.

Another concern is that firms are making claims under the mantle of respectability of the pharmacist. Some pharmacists have said that there is increasing pressure to make claims for non-medicines, a practice which could breach their code of ethics. Pharmacists have also reported being unable to control their sales assistants, who they say are making unsubstantiated claims about the medical powers of non-medicines when pressed by customers.

Personal testimonies

Freedom to use personal testimonies about the curative powers of a product is exploited by some companies. In a single publication sent out by one firm, individuals claimed that the same product had rid them of high blood pressure, intense depression, periodontal disease, fibrositis, period pains, menopausal hot flushes and other diseases.

Head of the Health Food Manufacturers' Association, Maurice Hanssen, says it is hard for companies to stand by while their less scrupulous rivals win business: 'We have had a lot of problems from our members because certain companies have been doing outrageous things for years and we haven't been able to stop them'.

HealthWatch believes that making medicinal claims for which there is little good evidence is wrong. If the claims are false then patients could be harming their health or being discouraged from seeing their doctors, who might have diagnosed serious conditions. HealthWatch believes that medicinal claims for which there is little evidence falsely raise people's hopes. At the very least, hopeful patients are

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wasting money by making decisions based on little evidence.

In the UK, people believe that they are protected by legislation against weakly supported or unsupported claims about the medicinal effects of alternative products and orthodox medicines. This faith dulls their natural scepticism and makes it all the more important that the protection is there.

Advertising a medicine is subject to strict laws. A company or person that makes a medicinal claim for an unlicensed product in a magazine or newspaper advertisement would probably initially be warned by the ASA. Although there are those who do this, this newsletter is more concerned with exposing those people who have found other, more insidious methods of getting across their claims.

In this issue of the HealthWatch Newsletter we look in some detail at the various ways that disinformation can be deployed to promote the sale of products not allowed by Medicines Act legislation to make a direct claim of medical benefit. To do this, we commissioned the journalist Aisling Irwin to identify and make a systematic study of a number of "hidden persuader" techniques. The report of this study makes up virtually the whole of this issue.

Our mission is to enhance informed choice through reliable information. We feel that wider understanding of the way in which untested claims can be made permits the consumer to exercise that cool judgement necessary in the "buyer beware" situation in which these promotional suggestions are made. It seems unlikely that the Government will provide the resources needed for more effective control of advertisers who get around the protection which the Medicines Act was intended to give the public.

The existence of organisations able to exercise some form of discipline over their members gives some encouragement, but the history of voluntary control over subjects as diverse as financial advice and plumbing does not lead to strong hopes that discipline is easily imposed. However, Ms Irwin found that reputable individuals within voluntary organisations are very unhappy to see poor behaviour that could reflect back upon themselves and harm the public. They were eager to inform the Newsletter about abuses.

Disturbing

There were a number of really disturbing findings; even members of the committee who thought they had already met most abuses found themselves hearing about new ones. With so much ingenuity applied to sales promotion, it is unlikely that either voluntary or governmental control will be able to keep up with what is going on in these markets. One of the dangers highlighted by Ms Irwin is that the mantle of effectiveness will be conferred upon some products by their acceptance for sale through pharmacies. An essential role of such professionals is to act as learned intermediaries and it is not surprising that a special cachet is given to claims that appear to be endorsed by them. Pharmacists have traditionally been a conservative and independent group, only marketing products in which they have some faith. However, a prerequisite for the exercise of the restraint and judgement which would mean that claims are carefully evaluated before an item is stocked is that the pharmacist shall be earning enough from professional activities to ensure that commercial pressures have no influence. The pharmacist, like other professionals whose remuneration is controlled by the Government, is under heavy income pressure because of the way in which contracts are being renegotiated.

For the buyer to beware, good information is essential. HealthWatch hopes this contribution to the process will be helpful.

Michael E Allen

Books substitute for advertising

Health shops are bulging with books on the healing powers of ancient exotic extracts and the unexpected curative abilities of newly discovered vital bodily constituents.

Freedom of speech ensures that books are more or less free to make these claims. The Publishers Association has assessed legal liability for authors and publishers for inaccuracy and mis-statements in books and journals. It concludes that 'on the whole, the risk for publishers is relatively low'. The risk is greater if readers are expressly invited to rely on a book. If you are urged to abandon your doctor and stick to the author's recommended therapy, this increases liability.

But the situation changes when a manufacturer sends out these books to support its product. Pharma Nord (UK) sends free to people who reply to its advertisements a book called 'Q10 - Body Fuel' by Dr Knut T. Flytlie and Torben Dhalvad.

Claims in the book include: 'Ubiquinone has also proved to be effective in the treatment of periodontal disease, high blood pressure, diabetes, myopathy, and immunological problems.'

The Medicines Control Agency says: 'If the literature has medicinal claims in it then we say that it makes the product a medicinal product. We are already implementing this.'

Warning

Adrienne Mayes, administrator of the Health Food Manufacturers' Association's code, says that the Association now warns its members off this kind of activity: 'Everybody is entitled to write books but it's how you use them. The real criterion is connecting any claims to a product.'

In the case of PharmaNord, HealthWatch is not aware of any links between the company and the authors of the book. But in other cases, books on the market are not necessarily by independent authors.

One public relations consultant for the food supplement industry told HealthWatch: 'You'll find hundreds of books on individual vitamins, minerals etc. It's true that in many cases, when you look back to investigate the authorship, if a company manufactures or distributes it then it will have instigated publication - they'll have at least been consulted.'

If the book is not independent then sending it out to support a product goes against a recent European Court preliminary ruling. A herbal tea seller was invit-

ing people to write for further information to a foundation, which he also owned. Those who wrote received a booklet that claimed that the herb could prevent and cure cancer. The court ruled that this turned the tea into a 'medicinal product' - and therefore it had to obey any laws governing such products.

Thus even if a product's therapeutic properties are described in documentation such as brochures or books produced by a third party who is not acting totally independently of the maker or supplier, it is deemed to be a medicinal product.

Some companies are supplying books from distributors or publishing companies with different names and sometimes with different addresses. There is a book on sale in pharmacies called: 'Selenium Update...How it protects against cancer, heart disease, arthritis and aging'.

Cancer

The book contains statements such as 'Selenium prevents cancer.' The book gives a company name and address for ordering more supplies. The address is the same as that of Wassen International, which sells Selenium-ACE.

Wassen also offers the book for sale to people who answer their advertisements, through its 'mail-order arm'. Wassen told HealthWatch: 'We're not publishers or distributors of the book. We do sell the book purely because people often say: "What does Selenium do?" and we're stuck - and so what we have done is we sell it to people.' Wassen also said it was concerned to ensure that it behaved in a legal manner and that it might have to stop sending out books in this way.

If the claim 'Selenium prevents cancer' had been made in an advertisement, the ASA would have objected: 'A categorical claim like that would not be acceptable in an advertisement,' says the Authority. It is also illegal to advertise to the public on the treatment of cancer.

In some cases the Trade Descriptions Act forbids the use of books. Keith Hale, senior executive officer of the Local Authorities' Co-ordinating Body on Trading Standards, says: 'In terms of a book on a product being next to that product in a shop you would need the book and the supplement to have a similar or identical name and be produced by the same company. It needs to be a pretty close link.' Books sent out by post in support of a company's product would probably be considered to be advertising and therefore misleading and false claims could be dealt with under the Act.

Pharmacists pressured into medicinal claims

Some pharmacists are worried that they are breaching their Code of Ethics by stocking and selling increasing numbers of supplements and alternative remedies.

The fears come as Boots has decided to boost its sales of homeopathic products and train pharmacists to give advice on homeopathy.

Many pharmacists do not believe that there is enough good evidence of the benefit of homeopathic remedies. There is also disagreement amongst homeopaths about whether over-the-counter, mass-produced products are effective compared with products prescribed to individual patients by their practitioners. As HealthWatch has noted (Newsletter no.5, August 1990), a principle of homeopathic treatment is that the skilled homeopath determines a particular treatment for an individual patient.

The pharmacists' Code, published by the Royal Pharmaceutical Society, says that a pharmacist must not 'purchase, sell or supply any medicinal product where the pharmacist has any reason to doubt its safety, quality or efficacy.'

Brian Harrop, a community pharmacist in Blackpool, is worried that he would be breaching the Code by selling many products that pharmacists often sell, including homeopathic products. When he consulted the RPS about his fears of homeopathic products, it replied:

'Within this context there must be an objective threshold to a pharmacist's reasoning. The subjective views of a pharmacist are more relevant with regard to homeopathic medicines and this therefore leads to differing opinions within the obligation of the Code of Ethics stated above.'

Harrop says: 'I consider that we're a profession of scientists. If I am even selling a product then I should be able to justify selling it in a scientific way. I can't believe that anyone with any scientific training can just consider his own subjective views. The RPS has said that it will alter the definition of effectiveness to a non-scientific definition.'

The RPS told HealthWatch: 'We decided that it wasn't necessarily a vexed area. These things are purity-tested and it wasn't felt that there was such a potential for harm.'

The pharmacists' Code insists that: 'A pharmacist has a professional responsibility to exercise control over all medicinal and related products which are purchased or supplied.' Harrop is concerned that pharmacists who work for multiples, and who feel that stocking a particular product is in breach of their Code, should be able to exercise this responsibility.

Fears that pharmacists are giving advice for which there is little good evidence are supported by the following conversation in a pharmacy. The interview was between a pharmacist and a woman who believed that her child (not present) had bad hayfever. The mother asked for 'whatever's the most

efficient' for treating hayfever. The pharmacist replied:

'Whatever's the most efficient? Yes...the conventional ones are OK to prevent the symptoms...the homeopathic remedies take a little bit longer to work but sometimes have a better cure rate.'

'Really?'

'Yes'

'Well, I'll try the homeopathic ones. I know the doctor won't prescribe that, will he?'

'No, no he won't prescribe that.'

The pharmacist was not a trained homeopath. HealthWatch asked him if the product that he sold to the woman could prevent hayfever. The answer was:

'Yes - it builds up your energy. And so, with time - and it may take a few years because hayfever's one of the worst things to treat because it's very deep - you can get to see an improvement.'

Claims about cure and prevention can also be made by shop assistants. A pharmacist has recently written to the Pharmaceutical Journal to say that he is worried about the medicinal claims that are made by pharmacy sales assistants under customer pressure.

Just getting a product onto a pharmacist's shelves gives it the kudos of efficacy, safety and quality. The RPS is worried that customers assume that products that are sold in

pharmacies are known to be safe, when in fact there is little safety evidence for some of them.

Pharmacists can normally be relied on to warn customers of the contraindications of the medicines they buy. Customers may therefore infer that the same pharmacist's safety net hangs underneath the herbal remedies and food supplements that they buy in the pharmacy. In fact, the pharmacist simply does not know whether there are adverse effects from these products and, if there are, which groups of people are at risk, says the RPS.

'If you go into a pharmacy and pick up a Lemsip and a packet of paracetamol the pharmacist will say: "don't take both at once",' says Beverley Parkin of the RPS. 'But I'm not sure how many are experts in phytopharmacy and can say: "don't take x if you have high blood pressure".'

'Pharmacists have in their heads information about medicines in common use...because technical data about medicines and combinations is available. What we don't have with unlicensed medicines is any data. The data we want must come from independent testing of the sort which you need in order to become licensed.'

The RPS receives questions from pharmacists about how to advise on these products. 'It worries us a great deal,' says Parkin.

Product names

Product names can confuse

Evocative names that imply medicinal effects are appearing on bottles and packets. No medicinal claims are made anywhere else on the packaging because this contravenes the law.

There is 'Osteocare' (from Vitabiotics) and 'Porosis-D' (Cedar Health). One product that makes no claims whatever on the packaging, and just carries information such as where the capsule was made, what it contains, dosage (six per day) and a description of the company. The name, however, is 'Phytomenopause' (Arkopharma). There is also 'Menopace' (Vitabiotics).

There is the logo 'PMT', which is widely understood to be an acronym for 'pre-menstrual tension' but which one company expands to 'pre-menstrual time'. 'PMT' appears on at least two products.

There is Phytomemo (Arkopharma). The manufacturer of IQ tablets was successfully prosecuted a few years ago by trading standards officers because the name implied that the tablets could boost IQ.

FDA acts

The Food and Drugs Administration in the USA has in the past seized products bearing similar names to these because of fears about their implications. One example is a product called Osteocap.

If the name is used in an advertisement, the ASA says: 'If the product has a very strong implied claim that is purely put across by the name but not the ad we would want to see what clarification there is in the ad to show that the name doesn't make that implication.'

Public relations avoids legal problems

Some companies have turned to public relations companies to publicise their claims as editorial in newspapers and magazines, to avoid restrictions on advertising medicinal claims.

One public relations consultant who does work for alternative product companies says: 'The reason that a company employs a company like us is to say things that they can't say legally. We tell journalists. We work with companies who will provide us with scientific literature which they can't release themselves because of legal reasons. We do that and then you have to step back and hope that the journalists concerned are good at their job.'

Power of PR

The power of PR to get across otherwise prohibited medicinal claims is illustrated by one company's account of the promotion of a PMT product. There are still battles over whether or not PMT exists, let alone whether there is good evidence that any of its treatments work. Nevertheless myriad food supplements and alternative cures make huge amounts of money - evening primrose oil, for example, which some women buy when they believe they have PMT, commands a market of £32 million.

The Public Relations Business, a PR firm, has proudly described in a PR magazine its success in promoting Magnesium-

OK, manufactured by Wassen Nutrients, for the treatment of PMT:

Objectives included: 'to educate women in the benefits of magnesium as a proven alleviator of PMT symptoms'. This was to be achieved by 'enlisting medical endorsement for Magnesium-OK' and by 'editorialising the benefits of magnesium to PMT sufferers'.

The result of this campaign was that business rocketed: there was coverage in 145 publications and there were 50,000 requests for sample packs and product leaflets. Sales increased by nearly two thirds.

Wassen said at that time in a press release: 'Our decision to launch Magnesium-OK meant that we were able to offer consumers a product which is affordable and which gave a fast return to the retailer.'

The hugely successful Kwai garlic tablets became the fastest-selling dietary supplement within six months of being launched in the UK, five years ago. According to Marketing magazine: 'As in all success stories, there's a catch...Unless it is licensed as a medicine, no direct medical claims can be made on its behalf.'

The secret of Kwai's success, according to Marketing magazine, was: 'First and foremost, its direct appeal to anyone who is worried about the risks of heart disease...it linked the brand name to the idea of health as endorsed by medical re-

search; the idea being to hit the market with all the kudos of a licensed drug.'

Research on garlic

Kwai's parent company has invested heavily in research and there are published results of clinical research including placebo trials. In this way it has associated its product with medicine, according to Marketing. But this research has never been subjected to the kind of testing to which research on medicines with product licences has been subjected. There is research on garlic and heart disease, for example. Yet, another garlic product that has been granted licensing as a medicine has only achieved that licensing for the relief of cough, colds, flu and catarrh. If an advertisement is so similar to the publication's editorial content that it might be mistaken for it, it must carry the title "advertising feature".

If an article appears in a publication as editorial, and no money has changed hands in order to get it into the paper, then it is not an advertisement. Caroline Crawford, of the Advertising Standards Authority, says:

'Problems come with articles that are actually written by journalists where they have just picked up all the information from the literature from the company. Those are very difficult because they are editorial and they are sometimes used by newspapers and magazines to attract certain types of advertisers to that page.'

Freephone lines

Freephone lines offer privacy for strong claims

Tucked away from day to day scrutiny are phone lines that have been set up by some companies so that potential customers can hear more information about their products. The telephone numbers are found in advertisements or sent to a customer once he or she has replied to an address for more information.

On an information line to Blackmores, manufacturer of 'Celloid' minerals, HealthWatch asked for advice about a woman who, Blackmores was told, was going through the menopause and whose doctor had told her that she had osteoporosis. Blackmores was told that she had tried HRT but did not like it:

To help the osteoporosis, HealthWatch was told that the woman should take a Blackmore's silica compound: 'It will make sure the calcium's getting to the right place and in

the areas [of bone] that can actually be reformed there will be certainly some improvement. But one thing it does do, absolutely certainly is that it stops it getting worse...and it can actually deteriorate very very quickly.'

'And it might actually improve it?'

'Absolutely'

Blackmores said that the woman should also take Bio-Calcium because she needs a calcium supplement. She could take a Blackmores magnesium compound: 'if she's in a lot of pain it acts like an aspirin'

The woman was also recommended to take Dong Kuai, a 'hormone balancer' which 'will sort out all of the hormonal problems'. '...if you are producing too much of one hor-

mone and not enough of another one it tends to bump some up and bring some others down so they're more on a level as they should be.' It 'will probably go a long way to helping also with the osteoporosis and the menopausal symptoms'.

'So that will do things like get rid of the hot flushes?'

'That's right and all of the other nasty symptoms of the menopause.'

On another line HealthWatch was recommended a product that would stop the inflammation of sciatica and get rid of the pain.

The Local Authorities Co-ordinating Body on Trading Standards says: 'An oral statement that is false is a false trade description so it would be an offence.'

Press cuttings used as advertisements

HealthWatch has discovered a company that sends potential customers brochures of press cuttings, some of which make radical medicinal claims about its products. For the reader, the brochure appears to show that independent publications from diverse places support the products. Thus, medicinal claims are made that do not

appear to the reader to be advertisements instigated by the company.

'If the newspaper article is sent out by the company, making claims that encourage people to buy their product, then that's going to go against the law,' the Medicines Control Agency told HealthWatch. Journalists have

the freedom to report medicinal claims in magazine and newspaper articles. But when a company sends out these articles it is deemed to be making those forbidden medicinal claims.

Brochure

In magazine advertisements for "Bio-Quinone Q10" and for "Bio-Selenium+Zinc" the advertiser, Pharma Nord (UK), invites the reader to write or to freephone for further information. HealthWatch did this. A brochure, entitled 'What The Press Said...' was sent by return of post. This was full of reprints of articles from newspapers and magazines, mainly Danish alternative health magazines (translated into English). The articles' headlines included: 'Osteoporosis Can Now Be Prevented!'; 'The ageing process can be delayed' and 'How I found a cure for the common cold'. The article, 'Osteoporosis Can Now Be Prevented!' carries beside it a photograph of a woman holding a packet of "Bio-Calcium".

Vanessa Collier, of the National Osteoporosis Society, says that the Society is worried by many claims about the cure or prevention of osteoporosis, which can be a very serious condition. 'They lead to people self-diagnosing themselves and then treating themselves. These people are then not discussing the problem with their GPs to find the right cause. The dangers are the same for treating other menopause-related problems.'

Worried

The Advertising Standards Authority says of some of the statements in the brochure: 'If they were in advertisements then we would challenge them.' The Health Food Manufacturers' Association, says: 'In terms of sending newspaper cuttings and books to the public, we tell our people not to do it. We are very worried about Pharma Nord.'

prevention or cure can lure people away from their doctors.

Maurice Hanssen, of the Health Food Manufacturers' Association, said of the leaflet: 'Frankly I think it's outrageous.' He said that companies should consider the legality of what they were saying, over and above their beliefs about the rightness or wrongness of their claims.

Mail order

Mail order claims worrying ASA

The Advertising Standards Authority is particularly worried about medicinal claims made by mail order firms.

'The mail order trading companies have made much more extravagant claims. They buy products in from other companies and draw up their ads from the sales literature from those companies,' says Caroline Crawford, of the ASA. 'Some have put ads together in a catalogue and mailed them out to people.'

Mail order advertisements for slimming patches are under investigation by the ASA because the claims made for them are 'in obvious breach of our guide' says Crawford.

Complaint

A complaint was recently filed with the ASA, for example, against Odhams Leisure Group Ltd and a mail order catalogue, Health Direct. The complaint, lodged by the Health Food Manufacturers' Association, was about efficacy claims in the catalogue for products including evening primrose oil and herbal night tablets. The complaint was upheld. Health Direct told the ASA that it had used wording suggested by its suppliers.

A catalogue from the mail order firm, HealthLink, lists products from many different companies. The list includes 'remedies' for bronchitis, colitis, obesity; it lists cold and influenza prevention tablets and biochemic remedies for migraine, fibrositis and varicose veins.

Leaflets about products can be ordered from mail order companies - and they can make significantly stronger claims than those that come directly from the company. HealthWatch ordered from HealthLink a free leaflet on Health Innovations' product, Kervran's Silica. The leaflet was written by Leslie Kenton.

After describing how our fruit and vegetables are now depleted of silica in its organic form, Ms Kenton says that Kervran's Silica can benefit humans and animals in 'so many ways it is hard to list them all.' One way that is listed is under 'Kervran's Silica Against Osteoporosis', where Ms Kenton says that it can help 'to protect against osteoporosis naturally'.

Serious condition

Osteoporosis can be a very serious condition. The National Osteoporosis Society is concerned that claims for its

Leaflets tell what packaging can't

Deluges of leaflets and booklets on the shelves of pharmacies and health food shops are promoting products that are often a hair's breadth away, sometimes using medicinal claims that are not permitted on the packaging. The claims exploit weaknesses in the enforcement bodies by sailing much closer to the wind than does the wording on the packaging or in advertisements.

Chairman of the Food and Drinks Federation law group, Alan Turner, says: 'There's a loophole where they don't make the claim but sell the products alongside material which is saying that this kind of component may do that or *probably* does that.'

Many of the leaflets praise the virtues of homeopathy. Some just introduce the reader generally to homeopathy. But some make long medicinal claims that are not supported by good evidence and others make their claims without saying who they are. One claims to have been recommended by a foundation that turns out to be funded by a manufacturer of homeopathic products.

Mass-produced homeopathic products are sold over-the-counter in health food shops and pharmacies. Indications about what they should be used for are not on the packaging. Instead, charts are provided at the point of sale, telling the customer what the claimed actions of the products are.

'Homoeopathy for the family' introduces the reader to homeopathy. Most of the booklet is a guide to the selection of homeopathic medicines for about 150 symptoms. The booklet says: 'Recommended by Homoeopathic Development Foundation Ltd' - but this foundation closed between a year and 18 months ago. The booklet is published by a company called Wigmore Publications. The man who looks after the administration of Wigmore, Peter Warren, works for A. Nelsons. A Nelsons is a major manufacturer of over-the-counter homeopathic products. Peter Warren said, "I actually work for Nelsons but I'm looking after the administration for Wigmore, although it is a completely separate company."

Some leaflets appear with no reference at all to who has published them or to what evidence there is for what they are claiming. They just list ailments and remedies: Dr Andrew Lockie, of the Faculty of Homeopathy, which represents medically qualified homeopaths, says:

'There should certainly be a contact name and there should be an explanation of homeopathy on it.'

It can be very difficult to prosecute someone who places a leaflet that makes incorrect claims about a product in the same shop as that product. Prosecutions for point of sale leaflets are only likely to succeed if a very close link can be established between the leaflet and the product, according to the Local Authorities Co-ordinating Body on Trading Standards. Keith Hale says:

'The court has always shown itself to be very limited in terms of what it thinks these things are related to. For example, if the leaflet is on the other side of the store to the product then it would be difficult.'

How to register a medicine

Under the Medicines Act 1968, a medicinal product is one whose purpose is mainly the treating, preventing or diagnosing of a disease. 'Disease' here includes any injury, ailment or adverse condition of body or mind.

A medicinal product can also be a product that is meant for preventing or interfering with the normal operation of a physiological function or for contraception or inducing anaesthesia.

Product licence

Most medicinal products require a product licence. In order to get a product licence a company must demonstrate the efficacy, safety and quality of its proposed medicine. Performing the research programme and following the procedures laid down by law to do this can take up to 12 years.

During this period, says the Association for the British Pharmaceutical Industry, for every 5-10,000 potential compounds evaluated, only one will get as far as being granted a licence for use. Research and development costs of each new medicine now run at more than £100million.

Prescription medicines are subject to approval by the Medicines Control Agency (the government's licensing body) after laboratory screening, animal testing and closely monitored trials on healthy volunteers and patients.

The potential new medicine goes through four phases of clinical assessment in humans. In phase one a small number of healthy volunteers receive it; in phase two, 2-400 patients receive it; in phase three, 3,000 patients receive it.

If the results are satisfactory, thousands of pages of data are presented to the MCA, which will refer the evidence to the Committee on Safety of Medicines. The CSM may then recommend that the MCA should grant a product licence.

After the drug has gone into general use, phase four studies are done on many thousands of patients. Doctors assist companies in post-marketing surveillance by reporting back on new products and any adverse reactions are reported to the CSM using the Yellow Card System.

Borderline

Some medicinal products do not require licences under the Medicines Act. They do nevertheless have to obey the other parts of the Act. They are 'borderline' products and include some substances that are both medicines and foods. Specific curative or remedial claims about a disease are not permitted for exempt products. This includes using words such as 'alleviates', 'combats' and 'relieves'.

How to register a food supplement

A dietary supplement is classed as a food and so it need only comply with the Food Safety Act of 1990 in order to be suitable to appear on the shelves.

Many people find this unsatisfactory and over the last few years the UK has been studying how the situation could be changed. The Denner Report was produced, for example, by Howard Denner, chief scientist at the Ministry of Agriculture, Foods and Fisheries.

Directive

The EC is discussing a directive on nutritional supplements. Under discussion is an intermediary drug type status whereby dietary supplements are not pharmaceuticals but they do have to prove efficacy and safety to a degree. But it will be a long time before any directive reaches the stage of being implemented in member states. And meanwhile the UK cannot unilaterally prepare new laws as all national work towards legislation must stop when the EC starts devising legislation.

Safety information

The UK has contributed suggestions about the EC directive on dietary supplements. It proposes that there should be a list of substances that are prohibited for sale as dietary supplements.

Manufacturers or importers of dietary supplements should be required to carry out a safety assessment for each product that is marketed, says the UK. They should keep a dossier of safety information available for inspection by the "competent authority". Products covered by the directive are to conform to certain purity criteria.

The UK suggests that, for those substances known to be dangerous in excess, maximum daily doses should be laid down by reference to the undesirable dose. In order to minimise risks, maximum daily doses may be established as a percentage of the undesirable dose.

Labelling

Products should be labelled with specific instructions about the maximum daily dose. All those known to be dangerous in excess should carry some form of warning and also indicate the recommended daily dose as a percentage of the recommended daily amount (RDA).

The UK also suggests that if a substance could be unsafe for particular groups of consumers, then this should be mentioned on the product.

Advertising

Medicines

Medicines that require a prescription cannot be advertised to the public.

All medicinal products that can be sold direct to the public without a prescription must conform to the Medicines (Labelling and Advertising to the Public) Regulations 1978. In general these regulations prohibit advertising medicinal products that are for treating serious or chronic diseases.

No advertisements can be made about any substance that might lead to it being used to treat cancer, diabetes, any heart diseases or degenerative conditions associated with ageing, for example.

Exceptions

There are exceptions to these rules. For example, the product licence may specifically allow advertising to be addressed to the lay public.

Specified herbal remedies that are recommended for their traditional purposes can be marketed on the basis of satisfactory purity criteria alone. Homeopathic products can be marketed without an indication, provided their active ingredients have been diluted to at least one part in a million.

Alternative supplements

The key point is that the supplement must not make a claim that makes it a medicinal product - or it will have to obey the Medicines Act, for example by having a product licence.

Regulations

Supplements coming under the food laws must obey the Food Labelling Regulations of 1984. These regulations list certain vitamins and minerals.

If a substance is on that list you can say why it is needed by the body. But you cannot say that it prevents or cures a disease.

Claims about the maintenance of good health are allowed under the Regulations, but not claims about correcting 'adverse conditions'.

Where to complain

If you have a complaint about the promotion of a product, you can write to the relevant body at one of the addresses below.

The Director General Of Fair Trading

The Director General has powers under the Control of Misleading Advertisements Regulations, 1988. He can stop an advertisement with a court injunction. But he leaves most complaints to be handled through 'established means'.

The first of these established means is the country-wide network of Trading Standards (or Consumer Protection) Departments. The second is the Advertising Standards Authority. There is also the Medicines Control Agency of the Department of Health.

The Director General is likely to consider a complaint when it is so serious that it justifies an immediate injunction or when existing 'established means' have failed.

Complaints must be about advertisements that are likely to deceive people and that, because of this deception, are likely either to affect the readers' economic behaviour or to injure a competitor of the person whose interests are promoted by the advertisement. Deceptive advertisements include those that create false impressions, even if everything stated in them is literally true.

OFT, Field House, 15-25 Bream's Buildings, London EC4A 1PR

The Medicines Control Agency

The MCA has a staff of scientific experts who advise the ministers of health on registration of products and enforcement of the Medicines Act of 1968.

MCA, Market Towers, 1, Nine Elms Lane, London SW8 5NQ

The Trading Standards Authorities

These implement the Trade Descriptions Act of 1968, which makes it a criminal offence to make a false or misleading representation about a product - orally or in writing. The two offences under the Act are: applying a false trade description to any goods; and supplying or offering to supply any goods to which a false trade description is applied. A trade description can be direct or indirect and made by any means. Making a false medicinal claim would come directly under this Act as well as under the Medicines Act.

£5000 is the maximum penalty for an offence, but each mis-statement is a separate offence and most offenders make more than one mis-statement.

The central body for trading standards officers is the The Local Authorities' Coordinating Body on Trading Standards (LACOTS). Officers for the region where a misdemeanour has occurred can be found via your local authority.

LACOTS, PO Box 6, 1A Robert Street, Croydon CR9 1LG

The Advertising Standards Authority

The ASA supervises the British Code of Advertising Practice. The Code covers advertisements in newspapers, magazines and other printed publications. It also covers brochures and leaflets, including those that are mailed directly or distributed in shops. The Code does not include telephone communications, press releases, packaging (with some exceptions) or newspaper editorials, the latter even if they resemble advertising material.

Here are some of the rules that the ASA imposes about medicinal claims. No advertisement can:

- claim or imply the cure of any disease as distinct from the relief of its symptoms.
- claim to rejuvenate
- suggest that consumption or use of the product is necessary for the maintenance of physical or mental capacities, whether by people in general or by any particular group. (But it may highlight certain groups that are more likely to suffer from deficiencies of a food).
- make exaggerated claims for relief, in particular by the use of testimonials or other evidence unrepresentative of a product's general effectiveness.
- if it is for products such as herbal or homeopathic products, claim that they are totally safe

ASA, Brook House, 2-16 Torrington Place, London WC1E 7HN

Press Complaints Commission

If you have written to the editor of a magazine or newspaper to complain about a breach of the PCC Code of Practice, a satisfactory reply should be received within seven days. If this does not happen, you can write to the Commission.

The Commission was set up to ensure that British newspapers and magazines follow the letter and spirit of the Code, which was drafted by editors and adopted by the industry. The Code includes an undertaking not to publish inaccurate, misleading or distorted material.

The Commission tries to resolve complaints amicably. If this is not possible it adjudicates on complaints. An adjudication is published in the Commission's monthly report - and in the relevant publication if the complaint is upheld.

The Commission usually deals only with complaints from people or organisations who are directly affected by the matters about which they complain. Sometimes third party complaints are considered if the public interest is significantly affected. Complaints are usually only accepted if they are made within one month of either the publication date or the editor's reply to a complaint.

PCC, 1 Salisbury Square, London EC4Y 8AE

Conviction of Reverend Doctor Elizabeth Marsh

Mrs Elizabeth Marsh was sentenced to 6 months in gaol at Isleworth Crown Court on 25th May 1993.

Not an earth-shattering piece of news; no wonder it didn't make the national newspapers.

When, however, it is revealed that Mrs Marsh was also known as Dr Elizabeth Marsh, who began her medical training in Holistic Medicine in 1981 and acquired a whole host of degrees and doctorates in such diverse subjects as theology, parapsychology, homeopathy, hypnotherapy, anatomy and biochemistry, from such august educational establishments as the Western University College of Iowa, the Graduate College of Bedford Scholars, the United Kingdom Homeopathic (sic) Medical School and Acton College London, things begin to get more interesting. What could have been the crime that deserved such a severe sentence?

Mrs Marsh was found guilty of illegally importing a drug, Cancell (also known as CH6), and of issuing an advertisement in the form of a pamphlet entitled *Cancer and Aids*. Is there any hope left for us? The use of this notorious substance was described for the treatment of cancer, lupus, multiple sclerosis, Parkinson's disease, hepatitis, hemophilia (sic), sickle cell (sic), herpes, EBV and especially the AIDS virus.

A television programme, first shown 2 years or so ago on Sky Television, showed some people who believed that Mrs Marsh was God's gift to mankind: it also showed some who didn't. They included desperately ill people who were clutching at straws; exactly the people at whom *Cancer and Aids* was directed, and didn't know how to distinguish between real providers of health care and the false. This is a recurring difficulty, and one which may never be resolved completely. Constant vigilance is still the only safeguard.

Vincent Marks

Nutritional intervention

Trials in doubt

No-one can deny that a register of controlled trials of nutritional interventions is desirable, but why do this under the aegis of the *Journal of Nutritional Medicine*, which is not peer reviewed and is not listed in *Index Medicus*?

Moreover, nutritional experiments, other than in laboratory animals housed in individual cages, are difficult to control. The

In Memoriam

Brian Inglis

Brian Inglis, champion of alternative medicine, died in February. He was a former editor of the *Spectator* and presenter of *What the Papers Say* and *All Our Yesterdays*. Brian became interested in alternative medicine after being offered an article for the *Spectator*, and latterly believed in extrasensory perception and the paranormal. I met him after he championed an article I had written for the *Oldie*. He was sociable, hospitable, a good listener, totally without vanity, malice or prejudice against women, and ineffably kind. We probably had similar views on many things, in a round-about way: I think Brian regarded drugs and surgery as inappropriate for people's functional health problems. At the funeral - he wanted his friends to drink some bubbly to mark his passing - there was general amazement that he was 76; I had taken him to be about 60. He enjoyed good health and died suddenly, after writing an obituary for his friend the broadcaster Bill Grundy.

Caroline Richmond

HealthWatch AGM

The next HealthWatch AGM will be on the evening of Tuesday 12th October, 1993 at Regent's College in the Inner Circle of Regent's Park. We hope you will reserve the date in your diary. This year, we will be awarding the HealthWatch award to Geoff Watts of Medicine Now, a journalist we consider has made a serious contribution to "enhancing informed choice through reliable information".

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HealthWatch promotes:

1. Good practices in the assessment and testing of treatments, whether "orthodox" or "alternative";
2. Consumer protection of all forms of health care, both by thorough testing of all products and procedures, and better regulation of all practitioners;
3. Better understanding by the public and the media that valid clinical trials are the best way of ensuring public protection.

HealthWatch welcomes membership enquiries from those who share its aims. Membership costs £12 per year (£8 for students); £4 air mail supplement for those outside Europe.

Subscriptions

Annual subscriptions to HealthWatch are now due for renewal. Members will have received forms recently from the membership secretary. Please reply as soon as possible.