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MHRA REGISTERS HERBS AND CONSULTS HOMEOPATHS

THE MEDICINES and Healthcare products Regulatory Agency (MHRA), the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe, has just registered its 100th product under the Traditional Herbal Registration (THR) scheme which, they say, “enables consumers to make informed choice”.

HealthWatch’s John Garrow joined a dozen journalists at a press conference on 15th March in the MHRA’s new steel-and-glass office on Buckingham Palace Road, London. “We were told that regulating herbals is very difficult, because the vendors constantly change the composition of the product, and add rare (and sometimes dangerous) drugs,” he said. “The new THR certification mark, granted by the Intellectual Property Office, is designed to indicate herbal medicines that are (at present) safe and thereby, ‘enables consumers to make informed choice’”.

However at no stage were the journalists told anything about the efficacy of the herbal product. So Professor Garrow asked. “Without that information the consumer cannot make a truly informed choice,” he pointed out at the Q&A session run by MHRA Manager of the Medicines Borderline section, David Carter. Herbal treatments, came the reply, are not like prescription medicines which are of uniform composition, so it is not possible to assess the efficacy of a herbal product. If the consumer is shown that a herbal is safe that is much more important than its efficacy. So, pressed Garrow, are the MHRA worried that the THR certificate will be interpreted by the consumer as a guarantee of efficacy? The answer was short. It was, “No”.

The MHRA’s review of homeopathic labelling, promised in

Andrew Lansley’s statement last July, is under way as part of a wider informal consultation. In an update to their last verbal comment to the *HealthWatch Newsletter* (issue 79, October 2010), when we were told to expect results of the review by the end of 2010, the MHRA have now told us, “any changes to the proposals set out in this consultation will form part of the review of the Medicines Act. Changes to the Medicine Act, including to the labelling, will not take place until 2012.”

According to the MHRA press office, invitations to take part in the consultation were sent to over 200 private NOPs licence holders (manufacturer’s licences authorising a non-orthodox practitioner to mix and assemble unlicensed medicinal products) and to a list of 37 manufacturers and organisations (of which most would be considered to benefit commercially from the sale of homeopathic products). Details of the consultation are available on the MHRA website,¹ through which HealthWatch volunteered a submission of its own shortly before the closing date on 18th February.

Mandy Payne

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1. Review of Medicines Act 1968: Informal consultation on issues relating to the product licences of right (PLR) regime and homeopathy. <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/Othermedicinesconsultations/CON105929>

New CAM chair for Exeter University

A NEW UNIVERSITY-FUNDED chair of complementary medicine is to be established at Exeter University and it seems likely that the principle of critical assessment of CAM established by Edzard Ernst will survive beyond his retirement.

Edzard Ernst has led the department of complementary medicine at the Peninsula Medical School in Exeter since 1993 when he accepted the Laing Chair to become Europe’s first professor of complementary medicine. For the last 18 years the department has researched complementary medicine with an emphasis on efficacy and safety. In 2005 Ernst accepted the HealthWatch Award. He has now published over 700 papers in scientific journals, and has said that about 5 percent of alternative medicine is backed by evidence, with the remainder being either insufficiently studied or whose evidence shows lack of efficacy.

In recent years the department’s research has surveyed systemat-

ic reviews and meta-analyses of clinical trials, but has not performed a clinical trial for some time due to budget constraints. It is hoped that, after a transition period, the new Exeter chair will enable the work to continue with fresh funding.

“The plan is that I retire in May and a new chair will be created and funded by the University of Exeter. After May, I expect to continue to work with the university to help find my successor. In my view, this is a significant victory and I am delighted to have won this battle, albeit with the loss of post and income.” He thanks HealthWatch members for their support.

Mandy Payne

See page 5 for Professor Ernst’s assessment of complementary medicines available over the counter at local pharmacies

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news

SHOW YOU LIKE HEALTHWATCH ON FACEBOOK

MOVING INTO the age of social networking, HealthWatch now has a Facebook page. You don't need to be a member of Facebook to view the HealthWatch page, just copy the address below into your browser. But if you are a Facebook member you can also help promote HealthWatch by clicking the "like" button—that way, you create a link with your own page and can introduce HealthWatch to your visiting friends.

Please help to make HealthWatch's page more interesting by posting messages or uploading photos, especially if you have the chance to report back from events that would interest other HealthWatch supporters, or if you have any pics from the AGM you

would like to share.

For those HealthWatch members who have not yet ventured into Facebook, registering is easy and free. Go to www.facebook.com and fill out the form. If concerned about personal privacy, restrict access to the information you post on your own Facebook page—from your home page pull down the "Account" menu (top right hand side) and select "Privacy settings".

Our thanks to student representative Ross Mirvis for setting up the new page.

<http://www.facebook.com/pages/Healthwatch-UK/141350435410>

Prescrire "did not denigrate" eczema treatment

A VICTORY for free speech in France: a Paris court has ruled that the journal *Prescrire* did not "denigrate" the drug Protopic (tacrolimus).

The journal, the French equivalent to the UK's *Drug and Therapeutics Bulletin*, had advised that tacrolimus should be avoided in atopic eczema in view of its unfavourable risk-benefit balance. Manufacturer Astellas Pharma filed suit against *Prescrire* on the grounds of "denigration", protesting against the "erroneous, or even deceitful, nature of certain critiques contained in the disputed article". The judges of the Tribunal de Grande Instance de Paris found on 2nd March that *Prescrire*, "did not exceed the legit-

imate objective that it had set for itself, nor the expectation on the part of its subscribers to have access to a documented critical analysis on a subject which falls into the domain of public interest and healthcare safety". *Prescrire*'s lawyers argued successfully for the recognition of the right to information and the right to criticise, unimpeded by the official position of health authorities or by the kind of censorship that Astellas was attempting to impose. This right must nonetheless be supported by rigorous and fully documented analysis, which the court recognised was indeed the case with *Prescrire*'s article.

Mandy Payne

NEWS IN BRIEF

BIOETHICS has published a brilliant analysis of the features of homeopathy from an ethical perspective. Kevin R Smith, a senior lecturer at Abertay University in Scotland, balances the therapy's potential benefits of non-invasiveness, cost-effectiveness, holism, placebo effects, and agent autonomy against failure to seek effective health care, wastage of resources, promulgation of false beliefs and weakening of commitment to scientific medicine. Smith concludes that "homeopathy is ethically unacceptable and ought to be actively rejected by health care professionals." See the issue of Feb 14 2011.

<http://files.meetup.com/1782915/Against%20Homeopathy.pdf>

NICE IS reorganising their NHS Evidence website, and from May 2011 the CAM specialist collection's web pages will no longer exist. The current 30+ specialist collections will be reduced to three "Evidence Hubs" at a redesigned www.evidence.nhs.uk. Evidence-based healthcare information service agency Bazian, who currently supply the analyses of evidence underpinning media healthcare stories for "Behind the Headlines" on NHS Choices, have won contracts to run two of the hubs, the third will be run by NICE itself. CAM will no longer have its own evidence updates etc, but will contribute to those of other clinical areas. NICE will continue to engage with specialist community stakeholders through a new network of Evidence Associates who will contribute to the Evidence Update process or be involved in the production of feature articles for the Eyes on Evidence bulletin or press articles. Find out more about becoming an Evidence Associate by emailing frances.abebreseh@nice.org.uk

IT'S NOT JUST consumers whose perceptions of risk are affected by the way the statistics are presented, according to a new Cochrane Systematic Review. Even health professionals can be misled by different statistical presentations. Cochrane researchers reviewed data from 35 studies assessing understanding of risk statistics by both health professionals and consumers. They found that all participants

understood frequencies—e.g., where an effect is expressed as 1 out of 200 people avoiding a hip fracture—better than probabilities. Relative risk reductions, as in "the drug cuts the risk by 50%", were less well understood. People perceive risk reductions to be larger and are more persuaded to adopt a health intervention when its effect is presented in relative terms. Relative risk statistics do not allow a fair comparison of benefits and harms in the same way as absolute values do, concluded the Canadian researchers.

Cochrane Database of Systematic Reviews 2011, Issue 3. Art. No.: CD006776.

LORETTA MARRON, Australian health skeptic, has called on the Australian government to close a chiropractic paediatric clinic run by the Royal Melbourne Institute of Technology (RMIT) University for teaching "inappropriate and potentially dangerous techniques that target pregnant women, babies, infants, and children". UK science writer Simon Singh, and Professor Edzard Ernst, support the campaign along with Australian neurophysiologist Professor Marcello Costa.

<http://www.bmj.com/content/342/bmj.d1977.full>

A WARNING against resorting to unproven treatments for embarrassing conditions is in the *International Journal of Clinical Practice*. Editor Graham Jackson, a cardiologist, published a patient's invoice from the Society for Complementary Medicine in London. The consultation had resulted in a bill for £462.52, mostly for supplements such as fish oils, vitamins E and C, and coenzyme Q10. The patient, a 50-year-old successful coronary artery bypass patient presenting with erectile dysfunction, turned to Jackson after finding the society's treatment "totally ineffective". Belief in concept without evidence of benefit determines a blinkered therapeutic approach, writes Jackson. Happily, prescribed tadalafil 5mg daily, the patient described the final result as "remarkable".

Int J Clin Practice March 2011; 65 (3): 231-44.

IS THE HEALTH OF THE PEOPLE REALLY THE HIGHEST LAW?

HEALTHWATCH IS an organisation that concerns itself with ensuring that claims made regarding health care are true because health matters to people. And it matters a lot. This is reflected in the number of years doctors must spend in training to care for people's health. Last month I attended a conference in Westminster on the Government's agenda of GP commissioning, organised by GovNet. Despite outward appearances, it was a highly commercial, advertising-orientated event, which was not at all reassuring for those of us who were concerned about the future of our nation's health care.

One point of interest was raised by a professor who referred to a plaque on a wall in Elephant and Castle, down the road from my practice, which quotes the Roman philosopher Cicero: "The Health of the People is the Highest Law". With an audience of several hundred health care professionals and managers, he presumably felt he was preaching to the converted in affirming this strong historic statement. I, however, nearly choked on my coffee.

Now I need to be careful. As chairman of HealthWatch I do not wish to be heard to be denigrating health, and as a GP I do not wish to belittle my own profession. My consternation, of course, is at the use of the word "highest". Perhaps this was a piece of rhetoric that you might hear in a union meeting where the workforce are ennobled by the suggestion that society values them more than anyone else—firefighters, postal workers, rubbish collectors or possibly even tax collectors (who perhaps need this insight more than most). As such the statement is a light hearted, throwaway comment intended to boost morale.

Or perhaps it is an astute political observation, that from a politician's point of view being seen as a proponent of healthcare is the most important item to have on a manifesto if you want to be elected. In this sense it is a sort of populist agenda, which is getting closer to my concern.

" ... this vast definition of health would have to include effective postal services, sea walls and an Inland Revenue we felt at peace with."

Now of course you could define "health" to include all good things, along the lines of the WHO definition of health, "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". This approaches the Jewish idea of Shalom: peace in all aspects of our existence, morally, politically, emotionally, in our relationships, in our security, in our health and happiness.

The problem with this is that Cicero would then merely be enunciating a sort of tautology—that the highest possible state of well being for the people, is the highest law. But you see this vast definition of health would have to include effective postal services, sea walls and an Inland Revenue we felt at peace with.

To subsume everything under "health" does not allow space for these individual realities to breath for themselves. The more narrow definition of health relating to the functioning of our bodies, which most of us understand by health, then begins to subsume everything else and the resulting picture is of the "medicalised" or "therapeutic" society that we rightly fear. In such a world we start looking for answers to all problems in terms of medicine. So, for example, perhaps crime could be reduced if we could better understand the brain, and find an appropriate medication to "treat" it. Or perhaps happiness is best achieved chemically, as Aldous Huxley spelled out for us in his dystopian vision of the future, "Brave New Worlds".



For Huxley, the works of Shakespeare were an unwelcome intrusion into this dystopia, for they spoke of things of greater profundity than a chemically induced sense of well-being.

Whilst Huxley's nightmare may still be a long way off, it seems to me working in general practice that society increasingly resorts to medicine when things are not going right. In a fragmented society, people do not know who to turn to when things go wrong, and frequently turn to their GP. In the last few weeks, I have seen more than a couple of people whose principal problem is a struggle with the Inland Revenue. Now of course depression and stress do come under a GP's jurisdiction. But it is often for want of other solutions that people become stressed and depressed, and GPs spend considerable time "problem solving", such as helping people to find ways to resolve financial difficulties, manage their time, approach their employer, or relate to their spouse or children. But wait. Addressing the problems of the whole person, rather than just the presenting symptoms—this surely fits the definition of holism?

It seems to me that CAM practitioners exploit our delusion that health is the highest law. They back Cicero on every occasion. Whilst they are commonly credited with being "holistic", it seems to be the case that this "holism" is in fact subsuming all of life to some sort of medical (or pseudo-medical) model. Whilst a GP problem-solves by pointing outwards away from medical solutions in order to relieve distress, CAM prides itself in allocating therapeutic solutions to all of life's problems. It is, in fact, the very opposite of holism. It is in the interest of a CAM practitioner to create health problems rather than solve them, for the more "problems" there appear to be, the more likely the therapeutic intervention is to help. You may not have thought that the tingling sensation you sometimes get in your foot was a problem, but a CAM practitioner would do well to highlight this as a profound issue, clearly related (for example) to your ENT problem, as it is then more likely to be amenable both to the power of suggestion and the placebo effect. Osteopaths and chiropractors may tell you that your spine is out of alignment or one leg is shorter than the other, and that this is the source of innumerable maladies, because a few "manipulations" and perhaps some leg-pulling later and you will find your whole sense of wellbeing has improved.

No, the health of our physical bodies is not the highest law. It is the means to other far greater ends and is part of a much broader sense of well being to which we might aspire.

James May

Chairman of HealthWatch

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1. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

exposing misconduct

WHISTLEBLOWERS, MENTORS, MONITORS, LAWYERS: WHO ARE MOST TO BLAME?



EVIDENCE-BASED medicine (EBM) is quite a recent concept. When I qualified as a medical doctor 60 years ago I had been taught by professors who wrote textbooks. That was soon to change for the better. Intelligent and sceptical soldiers returned from the war having learned that professors and their textbooks were often wrong. Properly designed clinical trials could show that, although X was the treatment recommended in textbooks, both Y and Z were much better, so EBM was a better guide than out-of-date professors.

Now EBM faces a new threat. Yesterday I spent the day at the Royal College of Physicians listening to a brilliant set of experts talking about “Fraud and Misconduct in Medical Research”. This is a potentially fatal disease for EBM. If medical journals (which now replace textbooks in many specialities) report false information about the safety or efficacy of therapies, then it is bad evidence and will generate bad medicine. All the speakers at the conference agreed that fraud and misconduct was a serious threat to EBM, but there was no consensus about how often it occurred, who was most to blame, and what can be done about it.

As the audience came into the lecture theatre we had all been offered a blue leaflet (four pages of A4) that contained “Guiding Principles for Pharmaceutical Physicians”. These were that the interests of the patients always took precedence, that all information about patients was confidential, and that careful consideration must be given to the balance of risks and benefits in the proposed trial.

The Chairman at the meeting was Dr Richard Tiner, President of the Faculty of Pharmaceutical Medicine (FPM). The first speaker was Dr Frank Wells, a retired pharmaceutical physician, who is famous for his work on the strict regulations for the conduct of clinical trials of drugs or healthcare products. Both these speakers emphasised the importance of transparency. In an ideal world the sponsors of such trials should reveal the results of all the trials performed on the product. All the trials should be registered, so those that gave less favourable results for the product could not just disappear without a trace. Both speakers insisted that fraud and misconduct in medical research was rare. Dr Wells said that the evidence showed its prevalence was only about 1%. He described how the FPM has developed ways to detect and prevent fraud and misconduct, and that whistleblowers should be supported, not penalised.

“He presented 16 cases, backed by solid evidence. He named the senior medics who denied all charges and wanted to get rid of him.”

All this sounds very good, but our world is not ideal. In the real world there is no way researchers can be forced to reveal unpublished trials that did not give a good report on the product that they are hoping to sell. Pharmaceutical organisations will not allow regulators to scrutinise their “commercially confidential” data. Whistleblowers are still penalised, whatever the FPM says. It is impossible to measure the prevalence of misconduct, because it all depends on the definition of what is called misconduct, and what is dismissed as carelessness, accident or innocent mistake. And of course you cannot count all the fraud you never hear about.

The next speaker was Dr Peter Wilmshurst speaking on “The role of the whistleblower”. If the reader is not familiar with Wilmshurst’s CV his career as a whistleblower up to 2007 is described in a very substantial article in the *Medico-Legal Journal*.¹

As a registrar he did not go round looking for fraud or misconduct—the misconduct came to look for him. In 1982 he was a research registrar in a prestigious London teaching hospital. His

task was to find out if a new drug made by Sterling-Winthrop called amrinone had an inotropic effect on the heart (that is, make its contractions stronger). His results showed that it was not inotropic, and caused many adverse effects. He reported this to Sterling-Winthrop, who asked him to adjust his results so as to make the effect better, which he declined to do, so he was threatened with litigation.

Over the next decade Wilmshurst tried in vain to find someone in authority who would have the courage to confront the culprits. Senior medics saw no merit in making public the misconduct occurring among their researchers and the mentors of these researchers. It would damage the reputation of the institution and, as in the amrinone case, might land them in legal battles with the very wealthy pharmaceutical companies whose reputation also would be sullied. The result of this reasoning was one of which the medical profession should be profoundly ashamed. Whistleblowers were a nuisance. They were traitors to the institution which was employing them, and they should shut up or, even better, go away.

In 1996 I was editor-in-chief of the *European Journal of Clinical Nutrition*. I was very pleased to receive an invitation from the then *British Medical Journal* editor Richard Smith to a closed meeting at BMA house at which Dr Wilmshurst would present the evidence of dishonest research in London teaching hospitals. It was some years since Wilmshurst had left Northwick Park Hospital where he had been an excellent registrar. I had heard he was causing a lot of trouble in London with allegations of misconduct that were being hotly denied by senior staff.

I worried that he had now suffered a personality disorder and saw crime where there was no crime. I think most of the audience had similar misgivings.

That meeting was one of the really important events of my life (and I hope others present at the meeting feel the same). He presented 16 cases, backed by solid evidence. He named the senior medics who denied all charges and wanted to get rid of him. It was a wonderful presentation, and some of the audience (not me) were able to confirm that some of the events he cited were real. The tables were now turned: editorials were in the *BMJ*² and the *Lancet*.³

What happened in the next decade is recorded elsewhere.¹ We know that there was misconduct in research, but we do not know if it is decreasing or not. The question I want to tackle is that of who is most to blame, because if we knew that we would have a better chance to correct the problem.

I have listed the possible suspects: whistleblowers, mentors, monitors, lawyers.

Some whistleblowers are heroes (I put Wilmshurst in that group). But some are themselves guilty of misdeeds. An example is the scandal about the measles, mumps, rubella (MMR) vaccine. It arose because Andrew Wakefield submitted a paper to the *Lancet* claiming that the MMR vaccine was linked to neurological disorders in children. His assertion was enthusiastically supported by some newspapers, despite denials by the Department of Health, so vaccine uptake fell and prevalence of the relevant diseases increased. The work was later discredited, and the supposed link found to be non-existent; but the damage had been done. So we need to check

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complementary and alternative medicine

SHOULD PHARMACISTS BE PURVEYORS OF PLACEBOS?



WHENEVER CUSTOMERS enter a pharmacy they see shelves full of “alternative” medicines, such as homeopathic medicines, Bach flower remedies, aromatherapy oils, and herbal medicines.¹ Most people trust pharmacists;² a recent survey suggested that 51% of all respondents use their local pharmacy for healthcare advice.³ Therefore many consumers might assume, “if these preparations are sold by a trusted pharmacist, they must work.” But do they?

Homeopathic remedies

Most homeopathic remedies are so highly diluted that they contain no active ingredients at all. Sceptics therefore argue they are implausible nonsense.⁴ Today there are about 200 clinical trials of homeopathy. Collectively these data fail to provide good evidence that homeopathy is anything more than an elaborate “make-believe”.⁵

Bach flower remedies

Bach flower remedies are available in most UK pharmacies. They are produced by dropping flowers into a tank full of water which is then mixed with alcohol. Subsequently, the liquid is filled into little bottles and sold dearly. To assume that they do anything other than reducing the cash in the buyer’s pocket, would be far fetched. What is more, all the rigorous trials of Bach flower remedies have shown that they are pure placebos.⁶

Aromatherapy oils

Aromatherapy oils are available in many pharmacies. The term “essential” implies that the human body cannot do without them. The evidence, however, tells a different story. Aromatherapy typically includes a soothing massage which clearly is pleasant; but pleasant does not mean effective in a medical sense. In fact, the best evidence tells us that the oils applied make no difference at all.⁵

Herbal Medicines

Some herbal extracts do contain pharmacologically active ingredients. This means that, theoretically, they can both kill and cure. Several herbal medicines are demonstrably effective. For instance, St John’s wort alleviates depression, devil’s claw reduces pain and horse chestnut seed extract improves the symptoms of varicose veins.⁵ Other popular herbal medicines, by contrast, have been shown to be nothing more than expensive placebos: evening primrose oil, bilberry and goldenseal might be good examples for this category.⁵ Others again may actually be harmful: borage, black seed oil or comfrey, for instance.⁵

Comment

Why are so many placebos sold in pharmacies? Are pharmacists shopkeepers, mainly concerned about their profit, or healthcare professionals with an ethical responsibility? Recent comments such as “we aim to offer the products we know our customers want”,⁷ seem to indicate that the former interest is about to win the upper hand. This would clearly be contrary to patients’ welfare.⁸

Some highly motivated pharmacists have recently published articles tackling this thorny issue e.g., in *Chemist & Druggist*,⁹ and *FACT*.¹⁰ The profession of pharmacists, however, seems to remain divided in their attitudes towards alternative medicines: about equal percentages report positive as well as negative attitudes.¹¹

Yet pharmacists’ codes of ethics across the globe provide little room for manoeuvre. They invariably state that pharmacists must provide their customers with the relevant information about the products they sell, must tell the truth and must act conscientiously.¹² The pharmacists’ role, when selling alternative medicines, is thus similar to their responsibilities regarding the sale of any other over-the-counter medicine.¹³ This means pharmacists should know more

about safety issues related to the alternative medicines they sell.¹⁴ “Improving pharmacists’ ethical training and promoting ethical awareness and responsibility”¹⁵ cannot exclude alternative medicine.

As pharmacists are about to take on more responsibility in clinical care,¹⁵ their attitude towards selling disproven alternative medicines should be re-considered as a matter of urgency.

Edzard Ernst

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To receive, in pdf format, the latest summary of clinically relevant articles published by Professor Ernst’s department 1993 to 2010 please e-mail: eernt@pms.ac.uk

Visit the Department of Complementary Medicine at: <http://sites.pcmd.ac.uk/compmed/>

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consumer protection

FOOD FOR THOUGHT? EU REGULATORS REJECTING MOST HEALTH CLAIMS



WITH THE GROWING health-awareness of the public, food products sold in the UK are increasingly associated with nutrition and health claims such as “cholesterol lowering” or “immunity boosting”. A health claim refers to “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.”¹ Notwithstanding the increase in the number of claims, they are not necessarily substantiated with strong scientific evidence.

Hence in December 2006, the European Union adopted harmonized EU-wide regulations on the use of nutrition and health claims for foods.² A key objective of this Regulation is to ensure the accuracy and scientific basis of claims. Food companies within EU are required to submit applications for their claims along with scientific evidence to support their case, and the European Food Safety Authority (EFSA) is responsible for verifying the scientific validity of the submitted claims.

By 2010, EFSA had assessed and provided scientific opinion for more than 1,700 general health claims, out of 4,637 health claims clustered from around 44,000 similar health claims submitted between July 2008 and March 2010.³ Over 80% of the claims were rejected by EFSA.

How does EFSA screen the health claims?

After initial screening to exclude unclear, vague, or not properly described claims, scientific experts on EFSA’s Dietetic Products, Nutrition and Allergies (NDA) Panel will issue an opinion on the claim. The 4,637 health claims currently being assessed are “General function” health claims under Article 13.1 (see Table 1, below). Additionally, a small number of claims are submitted through Article 13.5 (44 received, 10 withdrawn, 26 adopted), and Article 14 (268 received, 73 withdrawn, 70 adopted).⁴

Table 1. Categories of health claims under Articles 13 and 14 of 1924/2006 EU Regulation

1924/2006 EU Regulation	Description
Article 13.1	“General function” health claims: regarding the role of a nutrient or substance in growth, development and body functions; psychological and behavioural functions; slimming and weight control, satiety or reduction of available energy from diet.
Article 13.5	“New function” health claims: based on newly developed scientific evidence and/or for which protection of proprietary data is requested. For these health claims authorisation is required on a case-by-case basis, following the submission of a scientific dossier to EFSA for assessment.
Article 14	Claims referring to the reduction of disease risk or to children’s development or health.

For the health claims so far evaluated on foods and food components, most of the favourable outcomes were related to functions of vitamins and minerals, fatty acids for maintenance of cholesterol levels, specific types of dietary fibre for blood glucose control, and

sugar-free chewing gum for maintenance of dental health.⁵ Rejected health claims were largely because of insufficient information submitted or poor quality of the information. The main information gaps highlighted by EFSA include⁵:

- “Inability to identify the specific substance on which the claim is based.” (e.g., claims on “dietary fibre” without specifying the particular type of fibre);
- “Lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of the functions of the body” (e.g., food with “antioxidant properties”);
- “Lack of precision regarding the health claim being made” (e.g., claims referring to terms such as “energy” and “vitality”);
- “Lack of human studies with reliable measures of the claimed health benefit.”

EFSA will finalise the evaluations of all “general function” health claims (other than botanicals) by the end of June 2011.

Probiotics industry

With virtually all probiotics health claims being rejected by EFSA, Yakult could not claim that its product maintained immune defences against the common cold.⁶ Danone, a major market leader, also has to withdraw its claims on Actimel and Activia regarding reduction of *Clostridium difficile* diarrhoea.⁷ Apart from the lack of sufficient evidence from human studies to support these claims as described by the EFSA Scientific Panel, probiotics also face the problem of specifying the substance in question. For instance, despite a dossier of 34 publications submitted by the German firm Töpfer GmbH (including 13 randomised controlled trials, six human observational studies and 15 non-human studies), its claim on the gastro-immunological benefit of bifidobacteria was rejected because the Panel could not establish that the four strains of bifidobacteria in the product were the same as those used in the studies.⁸ Heavily dependent on health claims, EFSA’s mass rejection of claims for probiotics will certainly influence the consumer market. The manufacturers are criticising EFSA’s lack of transparency and rigid application of pharmaceutical standard on food products which are only claiming supplementary health benefits.⁹ There was also scepticism about the independence of the Panel, given that all are part time and many could have had a conflict of interest with the industry during their career.¹⁰ EFSA is holding a series of consultations with food companies/stakeholders to explain how it is carrying out its work and to provide additional guidance to applicants, the first of which was held in December 2010 with focus on health claims related to gut and immune functions.

Nevertheless, the public should be protected against misleading health claims from manufacturers. In weighing the choices on functional foods, it may be more helpful to the consumer’s interest

to differentiate products with absolutely no scientific evidence from those with emerging evidence that is, perhaps, less robust or product-specific. Regulators would then focus on communicating the level of scientific support for the claims to consumers. For instance, the US Food and Drug Agency (FDA) adopted an evidence-ranking system to describe the scientific certainty of “qualified health claims” in 2003 (see Table 2, below).¹¹ After all, it should be borne in mind that empowering consumers to make informed decisions is important both to promote a culture of evidence based health claims, and to prevent undermining public’s perception on the authority of the Agency’s opinion.

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Table 2. FDA evidence-based ranking system for scientific data

FDA category	Level of evidence	Approved qualifying language
A	High	A claim that meets the significant scientific agreement standard indicates a strong, high quality, relevant and consistent body of evidence that is not likely to be changed by new and evolving science
B	Mode rate	“Although there is scientific evidence supporting the claim, the evidence is not conclusive.”
C	Low	“Some scientific evidence suggests (the claim). However, FDA has determined that this evidence is limited and not conclusive.”
D	Very low	“Very limited and preliminary scientific research suggests (the claim). FDA concludes that there is little scientific evidence supporting this claim.”

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Whistleblowers, mentors, monitors, lawyers: who are most to blame? ...continued from page 4

that the whistle signal is in the public interest.

“Mentors” refers to the sponsors of the research, and the academic supervisors of the researchers. These must bear a lot of the blame. Junior researchers who are often trying to produce a thesis, or are building up a portfolio of publications to support their claims for promotion, need supervisors who supervise. If there is something dishonest going on, and they do not know about it, they are colluding and deserve blame. If they do know about it and try to conceal it they deserve still more blame.

“Monitors” are those who have a responsibility to ensure that the research is honest. This includes deans of colleges, vice-chancellors of universities and (for registered medical doctors) the GMC. In many cases these grand people have woefully failed to be open and effective enforcers of high levels of honesty. Editors of medical journals may opt to act as monitors of misconduct, but they often dare not do so due to the threats of lawyers.

Lawyers may be indirectly involved in dishonest research by being engaged to gag whistleblowers, and thus allow misconduct to

go unchecked.

So what can be done to improve the situation? I think the first step is to provide protection for the hero-type whistleblower, and ensure that the monitors do not penalise them. The meeting I attended was held by the Royal College of Physicians. I think they are in the best position to set up super-monitors to oversee the correct distribution of blame where there is misconduct in research. I even had the cheek to make that suggestion at the meeting. I do not think they were at all pleased.

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treatments

HAZARDS OF MALARIA TREATMENT IN FOCUS

EVERY YEAR at least five people in the UK die from malaria. They will have travelled to areas where malaria is endemic such as the Far East, Africa and the Middle East, and failed to take effective anti-malarial protection. Two recent articles have highlighted developments in treatment for this dangerous disease, whose most effective remedies derive from naturally-occurring compounds.



Resistance to the common anti-malarial drugs is a problem in many areas, and can be exacerbated by simple failure to take adequate doses of the prescribed anti-malarial treatment. Not only can dangerous exposure result from carelessness on the part of the individual, but also from taking one of the many fake or sub-standard drugs sold in developing countries.

The mainstay of malaria treatment has always been a drug based on a naturally occurring compound: quinine. However a newer drug has been developed which is derived from an ancient Chinese herbal treatment in use for fever for over a thousand years. The plant's common name is Sweet Wormwood (*Artemisia annua*) and the derivative which shows promise in the fight against malaria is called Artemisinin or, in its water-soluble form, artesunate. The compound rapidly kills the mosquito-borne *Plasmodium* parasites that cause the disease, and is effective at several stages of their development. The WHO recommends that Artemisinin Combination Therapy (ACT) should be the standard worldwide treatment of malaria. Now a new Cochrane review of 9 trials, including 1,664 adults and 5,765 children from a variety of settings across Africa and Asia, supports the recommendation by concluding that taking artesunate for malaria is more effective than quinine in both adults and children, reducing the risk of death by 39% in adults and 24% in children compared to quinine.¹

"There is now enough evidence to be confident of these results in adults and children," said Peter Olumese of the WHO's Global Malaria Programme. "Intravenous artesunate is now being recommended as the treatment of choice for adults and children with severe malaria anywhere in the world."

But there is a fly in the ointment, so to speak. There is only one ACT licensed for use in the UK (Riamet). It is taken orally. Severely ill patients will not be able to absorb the drug taken by mouth and need to have it by intravenous infusion, as per Peter Olumese's recommendation above. However the only preparation of Artemisinin compound for intravenous use is made in the Far East and does not comply with international Good Manufacturing

Practice (GMP) standards.² As a result it is not licensed for use in the UK. It is however available in a few specialist centres, where patients treated with this non-GMP artesunate are being carefully monitored by the European Network on Imported Infectious Disease Surveillance (TropNetEurop, see www.tropnet.net/).

The important message is, of course, avoidance. If you are travelling abroad to a malaria zone, find out the current correct anti-malarial prophylaxis for the area being visited. If treatment is advised, it should be started a week before departure, and continued for four weeks after leaving the area. The website of the Hospital for Tropical Diseases gives the details (www.fitfortravel.nhs.uk).

People born abroad and re-visiting relatives after living for some years in the UK, may not realise that the immunity they had as children may have been lost, so they too may need prophylaxis.

Mechanical barriers (such as sleeping in a mosquito net) to prevent mosquitoes from biting are advisable, as is the use of chemicals (such as Deet) that keep mosquitoes away. The British National Formulary suggests that anyone returning from a malarious area abroad who develops a fever within three months must see a Doctor and declare their recent itinerary.

I hesitate to finish with the following personal experience as it has not been corroborated, but when on a lecture tour of the Far East my local colleagues suggested that eating another naturally-occurring compound—garlic—was effective in preventing mosquitoes from biting. I duly chewed a clove of garlic each day and certainly mosquitoes kept clear of me. So did my friends.

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