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Health supplements: R.I.P.

Millions of Britons take herbal vitamin and mineral supplements, either as a preventative measure or to treat specific ailments. But we may not be able to for much longer

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You feel shivery, your back aches, the glands in your throat resemble golfballs; it's only a matter of time until your nose starts streaming. What do you do? You could visit your doctor's surgery and brave a waiting room full of people who are in as bad a state as you, or worse, and wait patiently for a five-minute consultation with your pressured GP - only to be told that it's probably viral and you should go home to bed, or be given antibiotics that you most likely don't need. Alternatively, you used to be able to head for your local healthfood shop where, at no cost to the creaking, over-burdened NHS, you could get free, and often lengthy, advice from a helpful member of staff who would recommend an affordable combination of vitamin C, echinacea and zinc, a safe, over-the-counter supplement found to be effective by millions of users.

If you're one of those who find such remedies useful, however, you'd better start stockpiling now. A raft of EU legislation looks set to nip the natural medicine market in the bud: soon, that popular vitamin C, echinacea and zinc combination may not be allowed on the shelves. A shadow looms large over the alternative health sector. Estimates of the impact of this new legislation vary, but hundreds of vitamin and mineral supplements could be banned outright, while an as yet incalculable number of common herbal remedies will disappear unless consumers challenge it. The National Association of Health Food Stores claims that as many as three-quarters of its members could go out of business. The writing is on the wall for small British supplement companies, which will be forced to reformulate entire ranges and invest massively in applying for new product licences.

It's a scenario that is hard to take in. In recent years, so many more consumers have been turning to the health store in preference to the doctor's surgery that it had begun to seem a permanent fixture in modern life. Though there may still be the odd simple soul who believes that eating a clove of garlic can cure cancer, all sorts of perfectly sensible people who want to take greater personal responsibility for their health are finding solutions, or partial ones, at least, in natural remedies. Arthritis sufferers tired of conventional anti-inflammatory drugs that upset the stomach are looking to alternatives such as glucosamine sulphate and chondroitin. People prone to anxiety are choosing kava kava over Valium. Those who feel depressed are going for St John's wort in preference to conventional anti-depressants such as Prozac. Menopausal women are seeing black cohosh as an attractive alternative to hormone replacement therapy. The hungover take high doses of vitamins B and C (eg, in the popular Berocca

tablets). This surge is reflected in the media. Conventional "doctor knows best" columns have been eclipsed by alternative practitioners with a proactive attitude to health and a range of natural, nonpharmaceutical suggestions for the treatment of everything from cold sores to migraine.

All this interest is despite the fact that evidence of how - and, indeed, if - these remedies work is open to interpretation and incomplete. Some supplements are relatively well researched - two major epidemiological studies have shown that vitamin E supplements, for example, can reduce the incidence of heart disease by about 40%, while a substantial body of research suggests that antioxidant vitamins protect against certain diseases.

For other more obscure supplements, however, relatively little conventional medical research has been carried out, so evidence of efficacy relies more heavily on traditional usage. Much of the scientific work into rhodiola rosa, for example - a herb that is thought to make the body more resistant to stress - has been carried out in Russia, and a lot more research is needed to confirm the benefits that are claimed for it. Even so, it seems that growing sections of the public can live with this sort of uncertainty. More people are voting with their feet and concluding that alternative remedies work as well, or even better, than conventional drugs, with fewer, if any, side effects. But that option could be taken away altogether if the new EU legislation goes ahead unchecked.

The attack comes from four different pieces of legislation, one of which is already in force, another approved in principle. All are couched in the now familiar EU language of consumer safety and free trade. Currently, the UK, the Netherlands and Ireland have a far more permissive attitude towards supplements than other member states, and make available a wider range of higher-dose remedies. This approach is in line with those in the US, Australia, New Zealand and Canada. But those days are numbered. The idea behind the new regulations is that, irrespective of whether you are a healthy Cretan, living on fish, multiple fruit and vegetables and monounsaturated olive oil, or a typically sun-starved Brit, existing on nutritionally impoverished processed food, you should have the same range and strength of supplements at your disposal.

Attack number one comes in the form of the Food Supplements Directive, which will set maximum levels for vitamins and minerals. Currently, consumers in the UK can buy high-strength vitamins in dosages that are way above what's known as the recommended daily allowance (RDA). Far from being a formula for good health, however, the RDA is simply the minimum dose you need to prevent nutritional deficiency. RDAs were developed during the second world war, to ensure that soldiers did not get sick. Now, modern research into the positive health properties of vitamins and minerals is focused on safe upper levels, or "suggested optimal nutrient allowances" (SONAs), much larger doses that actively promote health, rather than simply prevent disease. The difference between the two is vast. The RDA for vitamin B5, for example, is just 6mg, but consumers in the UK can currently buy it in 550mg doses; and arthritis sufferers take it in doses as high as 1g-2g, and find it efficacious. Meanwhile, in most other European countries, a much more restrictive range of vitamin and minerals, based on the RDA, is available. A likely EU consensus might set limits at only two or three times the RDA, representing a liberalisation for most European countries, but decimating the choice available to the British consumer.

This "framework" directive has already been approved in principle by MEPs, most of whom were effectively voting as if writing a blank cheque; now that the full implications of the directive are emerging, however, many of those same MEPS are reported to be "flabbergasted". The all-important detail - the setting of new upper limits and an agreed "positive list" of nutrients - will be decided next spring. So far, some 300 popular nutrient forms from which thousands of supplements are derived are not listed. "This will wipe the most popular and effective higher-dose vitamins and minerals off the shelves," says Sue Croft of Consumers For Health Choice, the group that successfully campaigned between 1997 and 1998 against the proposed ban on higher-dose vitamin B6. "Millions of people will have their choices restricted or taken away."

The second attack takes the form of the Traditional Herbal Medicinal Products Directive, which says that herbal remedies can only be licensed if they can be shown to be safe and produced to high standards. That sounds reasonable enough - until you learn that herbal remedies will be licensed in the same way as drugs. A company making garlic capsules, for example, will have to go through many of the same regulatory hoops as a company producing a new pharmaceutical drug. Estimates for the cost of getting these herbal licences vary from £10,000 to several million pounds a product. This would almost certainly deter all but the largest companies from producing remedies such as St John's wort, kava kava, gingko biloba, red clover, rhodiola, evening primrose oil and ginger. There is no prospect of several manufacturers pooling resources to get an ingredient licensed, because each company's formulation will be treated as individual.

Furthermore, to get a licence, a specific product must have been on the market for 30 years, 15 of which must have been in Europe. The effects of that time bar are dramatic. Black cohosh, for example, an oestrogenic herb traditionally used by native Americans, has demonstrated results superior to hormone replacement therapy in the treatment of menopausal symptoms, with women who take the herb reporting fewer adverse events, even than those taking a placebo.

But black cohosh has only been available here for around five years, so, like any product introduced since 1973 - in other words, the most cutting-edge herbal products - it will become illegal. As yet unknown herbal remedies might never even see the light of day in Europe. "This is highly restrictive and racist," says Patrick Holford, founder of the Institute for Optimum Nutrition. "It could wipe out hundreds of really useful herbs, not on the basis of consumer protection or science, but on the basis of geography - herbs that have been used safely for hundreds of years in the Americas, Africa, India and China." In addition, any combination of herbal and vitamin/mineral products that natural medicine practitioners believe work better in synergy than apart, such as vitamin B6 with evening primrose oil, will be banned.

There's a third prong to the attack, in the form of the Novel Foods Directive, which is already in force. This was originally designed to control genetically modified foods and new, so-called "functional" foods, such as fish oil-enriched bread, but is now being applied to absolutely everything that is sold under food law. Any food product (which includes supplements) that was not on the EU market before May 15 1997 can only be granted approval after submission of a dossier containing huge amounts of technical and safety data. So far, a herbal sweetener and an immune system-boosting tonic have already been forced off the shelves as a result, and next in the line of fire is MSM, an increasingly popular organic sulphur

that has been found to be effective in the treatment of joint problems. What makes these developments even more worrying is that there is no appeals process under this directive.

The final attack seems on the surface to be an innocuous tidying-up of the EU Medicines Directive. But, in fact, it will mean that anything with a physiological action can be reclassified as a medicine - and under EU definitions, that means that any product sold in a health store, even herbal tea, could be deemed to be medicines, while items such as coffee and grapefruit juice (which also have proven physiological effects, but which are sold in food shops), will not be affected. So much for Hippocrates, who said, "Let food be your medicine." The new EU laws will say that a product must be either one or the other.

The authority in the UK charged with drawing this line is the Medicines Control Agency (MCA), yet it has a direct interest in classifying supplements as medicines - it earns 95% of its budget from licensing the latter. MCA committees are filled with doctors whose experience lies in conventional medicine. Many of them are either employees of pharmaceutical companies or are beholden to them for research grants. By contrast, the New Zealand government recently decided that its equivalent of the MCA is not qualified to consider natural reme-dies, while in Australia the Traditional Medicines Evaluation Committee made up of natural medicine practitioners, suppliers and scientists and applies different criteria to supplements than those it applies to conventional drugs.

Faced with this onslaught of hos-tile legislation, the UK natural health industry is smarting at what it sees as the breathtaking injustice of it all. A key principle of natural medicine is the Hippocratic requirement primum no nocere , or "first, do no harm". At the moment, supplements are sold under food law, which means they have to be as safe as a loaf of bread. The MCA already has the power to remove from the market any supplement it considers to be dangerous. Conventional pharmaceutical drugs, on the other hand, are sold on a costs versus benefits basis, the thinking being that the beneficial effects of the drug should be balanced against its risks. Side effects are simply an accepted part of the pharmaceutical package.

"There has never been a death due to vitamin and minerals in the UK," says Holford, "but thousands have been caused by conventional drugs. The risks are completely different." Or, as John McKee, who runs Hanover Health Foods in Edinburgh, puts it: "You can go to any petrol station and buy enough paracetamol to kill yourself. It's very hard to commit suicide in a healthfood store."

Yet EU commissioner David Byrne insists that the aim of the legislation is to "assure consumers that these products are safe and that doses available are not excessive and potentially dangerous". This echoes the long-running demonisation by the orthodox medical establishment of natural health practitioners as a bunch of cranks and charlatans, hawking useless and potentially deadly products to a gullible public.

If you believed recent headlines, then fears over kava kava, the traditional Polynesian remedy for anxiety, seem to lend weight to that viewpoint. "Shyness remedy ruins your liver!" screamed the London free paper Metro last December, and throughout the media reports appeared that kava kava had been linked to 30 cases of liver failure and death in Germany. The MCA put pressure on health stores not to

stock it, and it was promptly voluntarily withdrawn; it has been off the shelves ever since. Kava kava's future is now in the hands of the MCA and the Food Standards Agency (which has gone as far as issuing it with a health hazard warning), and a proposed permanent ban is out for consultation. The MCA claims that there is "significant existing evidence of hepatoxicity".

But delving into the details of those so-called casualties, the case against kava kava is deeply unconvincing. Most of the victims were already taking pharmaceutical drugs known to be toxic to the liver, and many were elderly heavy drinkers who had already abused their livers. "The vast majority of these cases involved hepatoxic drugs or alcohol," says Holford. "Of the remaining nine, five have spurious relevance to a safety assessment of kava kava for one reason or another, and four do not provide enough data to know if it was kava kava causing the problem." Holford, along with Dr Hyla Cass, associate professor at the University of California's school of medicine, has carried out a detailed review, which is consistent with the longest running study of kava kava to date, reported in 1997 in the journal Pharmacopsychiatry, which concluded that, "in contrast to both benzodiazepines and antidepressants, kava kava possesses an excellent side-effect profile".

"The MCA's double standards are abhorrent," says Holford. "A large number of published safety and toxicity studies clearly indicate that kava kava is far safer than conventional pharmaceutical anti-anxiety and antidepressant prescription drugs."

The MCA's cautious approach to kava kava contrasts with its attitude to the commonly prescribed family of drugs called Selective Serotonin Reuptake Inhibitors (SSRIs), of which Prozac is the best-known example. These have been blamed for suicides, murders and even mass murders in the US, and are the subject of ongoing litigation. In the UK, however, the MCA has resisted putting a warning on them. "The MCA liaises with pharmaceutical companies to decide what warnings might be appropriate," says Dr David Healy of the North Wales department of psychological medicine, who has been petitioning the MCA to issue some form of general warning. The drug firms, however, argue that patients on SSRIs are already high suicide risks, and that the warnings that accompany the medication are sufficient. "These are big players with tremendous incentives to defend their product," says Healy. "Small companies fighting off restrictions on herbs are at a disadvantage. They are small, they don't have exclusive ownership of the herbs, so they have less reason to do so, and they don't bite back."

Speculation is rife in the natural medicine world about the extent to which pharmaceutical interests are orchestrating legislation. Back in 1987, the Campaign Against Health Fraud (Healthwatch) waged an aggressive public campaign against natural remedies, financed initially by medical insurance and drug companies. Similar campaigns were waged in the US and Canada. And in the 1990s, there was a series of well-publicised attacks on food supplements. Now, there's a persistent rumour that PR agencies working for drug firms are spinning stories to the media, casting doubt on the safety and efficacy of natural alternatives.

Drug companies have a proven track record in trying to legislate the natural health business out of existence. In 1996, for example, the Ecologist magazine revealed that, when the Codex Alimentarius (the World Trade Organisation body that sets international standards for drugs, food, supplements, etc) met,

the German delegation put forward a proposal, sponsored by three German pharmaceutical firms, that no herb, vitamin or mineral should be sold for preventive or therapeutic reasons, and that supplements should be reclassified as drugs. The proposal was agreed, but protests halted its implementation.

That same lobby now seems to be powering EU legislation. According to the UK department of health, the impetus for the Traditional and Herbal Medicinal Products Directive came from the European commission's pharmaceutical committee. "No one is saying that the natural health industry does not need regulation," says Holford. "It has grown from a small niche to a major market sector. But this legislation is draconian. UK consumers now have experience of many years of safe and effective usage. They don't want supplements forced off the shelves or available only in ludicrously low doses."

And if consumers can no longer buy that helpful supplement in the health store, they may simply source them from unregulated internet suppliers. It might lead, say, to a new variant on the clothes shopping trip to New York: UK consumers who can afford it might go on supplements trips to stock up on remedies that are freely available in the US, but banned or unavailable here.

Surprisingly, in the 1980s the policy of the US Food and Drugs Administration was to reclassify supplements as medicines. This even led to a farcical situation in which armed FDA officers would raid clinics looking for illegal caches of vitamins. But public protest forced a change, and since 1994 the US has had a statute that guarantees both free availability of supplements and information about how they work. Similarly, in Canada, doctors in the 1990s were being struck off for prescribing vitamins and the government reclassified hundreds of herbal remedies as medicines. Following public outcry, however, they were all later declassified.

In the UK, when the government tried to withdraw higher-dose vitamin B6, it met with a similar reaction. Many MPs were staggered by the sheer volume of well-informed mail, and B6 was saved - at least until now. And the natural health sector hopes that it can play the same card again, with the same results: "There is still time to force changes to this ruinous legislation," says Croft.

To that end, healthfood stores are tooling up with Save Our Supplements petitions and leaflets, while celebrities such as Elton John, Cliff Richard and Paul McCartney have weighed in with support. The ranks of regular health store users are being mobilised. As consumers begin to realise the extent of the attack on natural remedies, the hope is that they will simply not stand for it. And heaven help any politicians who try to come between articulate OAPs and their glucosamine sulphate or angry hormonal women deprived of vitamin B6 and evening primrose oil