

The Medicines Act - death sentence for vitamins

Many people do not realise the true consequences of the threat from Europe to make vitamin supplements above nominal RDA value (and many other nutritional products and substances) subject to medicines legislation. This would not just mean enforced new routes of sale and distribution, but the extinction of over 95 per cent of products.

What is a medicine?

To be a medicine, a product has to fulfil certain criteria. These include being effective against one specific or several main symptoms, and producing side-effects. The logic here is that if a drug is to be active it must have side-effects. If the substance has no side-effects then it cannot be a medicinal product.

Since the vast majority of nutritional supplements have neither side-effects nor specific physiological action, they cannot be medicines. Despite this, however, in some countries nutritional products are considered medicinal.

Let us assume that the British government goes along with Europe and decides that these are medicines (and in so doing modifies its definition of a medicine) how will this bring about the extinction of the products?

Thalidomide

Medicine licensing was brought into being because of the Thalidomide tragedy in the early 1960s. The pharmaceutical profession had been pressing for greater control over medicines distribution before then, and therefore welcomed the prospect of more stringent legislation.

When the Medicines Act itself was actually passed, many pharmacists gained little. Ultimately the patients and consumers lost a lot and only the multinational pharmaceutical companies really gained.

Pharmacists had pressed for the legislation, but it backfired on them to some extent. Ever since, they have been pressing for more control, and have seen the area of supplements as one where they could possibly obtain a monopoly.

Unfortunately they do not realise that the intricacies of legislation mean there would be no supplements for them to add to their turnover, so they would have very little gain at the end of the day.

Licences

Why will supplements cease to exist if medicines legislation is applied to them?

Well, each medicinal product requires two important legal steps. There is a Product Licence and a Manufacturing Licence. A product with a licence must be made by a licensed manufacturer.

This may seem simple enough, but in fact it gives the bureaucrats a field day for interfering with product availability.

To hold a manufacturer's licence you do not simply have to work to the so-called GMP (Good Manufacturing Practice). GMP is linked to a very rigid product licence which under British law will not permit you to change the source of any raw materials, the specification of any raw materials, or the ingredients balance, without official sanction. This applies even to the most minor changes, and to all ingredients, whether active or inactive. The method of manufacture cannot even be marginally improved without sanction.

Commercially the manufacturer is in a straitjacket. He can't innovate. If a supplier goes out of business, he may have a long-term out-of-stock problem. If his supplier marginally changes the specification of an ingredient used in the product - in a way which he knows from

experience would have no deleterious effect on that product - he could again have an out-of-stock problem. He must apply for the change, scientifically prove the change makes no difference to the product, and finally pay for the right to change.

The officials do not have to react quickly to the problems. They have short hours and long holidays!

Affording bureaucracy

Whilst all this bureaucracy can be afforded by large multinational companies with drugs that cost the NHS £48 for six pills (the latest price for a new migraine drug from Glaxo) - for herbal medicines or vitamins (where perhaps 100 tablets cost a consumer £3-£4) things are very different.

Let us take Feverfew - a supplementary herb for migraine - as an example. For 90 tablets the cost to the consumer inclusive of VAT is £5. This would be a cost to a pharmacist of about £2.80 (excluding VAT) which would be the basic NHS cost if Feverfew were available on the NHS.

Let us assume that this packet of Feverfew would be sufficient for 15 migraine attacks. The cost per migraine attack to the NHS would then work out at about 20p.

The new migraine drug, at a basic cost of £48, is enough to treat 3 attacks, and therefore costs the NHS £16 per attack. Thus Feverfew, which costs the government nothing because it is not on prescription, would be one eightieth of the price of the latest drug. If you translate this by simple arithmetic, the £200 million business enjoyed by over-the-counter supplements would translate into a £16 billion drug business.

These are not extreme examples, but have been taken to illustrate what is at stake.

The Medicines Act - effects so far

As a result of the 1968 Medicines Act, with its commercially impossible licensing regulations, the British pharmaceutical industry is now dominated by a handful of companies - all of which have grown to great power in the 1980's as the generic companies (manufacturers of non-proprietary products) have declined. Many generic products in fact have to be imported because the British generic industry has become so unprofitable. Overseas manufacturers are not burdened with excessively rigid licensing and over-zealous inspectorates by their governments.

The herbal medicine product list has been drastically reduced. Tens of thousands of products have been lost because companies were just not able to answer the crazy and irrelevant questions asked about their products, by officials who had no experience of the natural medicines industry. Attempts to tell ministers that no experts appropriate to herbal products were employed within the regulatory body were dismissed at many meetings. At the moment, a change of heart is rumoured to be taking place, but I would not be too sure about this.

I said in 1973 that whilst they might be closing mental hospitals everywhere there was one opening at the DHSS in the Medicines Division! The department's experts were asking herbal manufacturers to meet product and manufacturing criteria which were more appropriate to sterile injectables than to natural substances like fruits and herbs. It was like asking a greengrocer to ensure that his potatoes had the specification of injectable dextrose before being allowed to sell them. After all, both are sources of carbohydrate energy to the human body.

Why has all this happened when the politicians just wanted to protect us from another Thalidomide? They have hardly even done that. Many drugs have gone through the full rigmarole of the full licensing system, yet still proved very unsatisfactory - for example, Opren, high dose contraceptive pills, tranquilliser drugs and many others. Indeed, many of them have wreaked havoc, and hospitals are said to be treating more people suffering from the side-effects of drugs than from natural illness.

Even paracetamol, under the guise of Anadin, has caused a recent death largely because of the negligence of the overpaid Medicines Control Agency (MCA) officials, who allowed a

licence for a group of products under a name previously associated with a single formula. This caused the patient to die. The doctors believed they were treating someone suffering from aspirin overdose, when in fact she was suffering from paracetamol overdose. No doubt documents submitted by the manufacturers of Anadin were very detailed in aspects that have little relevance to the safety of the product; yet the obvious problem was probably clearly stated on the first page of their submission. How can such officials and such a body command any respect?

Rebellion needed

The herbal industry should have rebelled years ago. That they did not reflects poorly on their leaders, who were too afraid of the financial cost to themselves and their own companies. They happily lost sight of what was going to happen in the future for the sake of expediency. Today, herbal medicine is stuck in the time warp of 1968 - no really new products have been introduced, and only a handful of those available in 1968 survive.

Many of the survivors are not the best preparations in their field - just products of the few richer companies. Yet those companies are not rich enough to provide us with new products.

If the supplements industry is not to go the way of the herbal industry, it must now stand its ground and refuse to become embroiled in inappropriate legislation for its products. There are other ways to meet political and consumer concerns. Whatever happens, we must insist that any regulation be in consultation with us, and that any subsequent body be staffed with people with real experience of our products and industry. At the moment no-one at the MCA has any experience or real knowledge of natural medicine, be it herbal, homoeopathic, anthroposophic or nutritional.

In Europe there is a good tradition of natural medicines which stands apart from the allopathic treatments. We should be sure our nutritional products will be given their special place too and not enjoined with philosophies with which they have no legitimate or historic connection. I hope the SPNT will continue its fight.

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