

CONSULTATION LETTER MLX 249

**Proposed Amendments to the MEDICINES FOR
HUMAN USE: (MARKETING AUTHORISATIONS
ETC.) REGULATIONS 1994**

REPLY FROM

**THE SOCIETY FOR THE PROMOTION
OF NUTRITIONAL THERAPY**

30 December 1998

The Society for the Promotion of Nutritional Therapy is an independent organisation which receives no funding from the vitamin industry.

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In this draft legislation, which has not to our knowledge been subjected to any prior consultation procedure with interested parties, the Medicines Control Agency (MCA) proposes to give itself the sole statutory right to interpret medicines law with respect to the defining of products as medicinal. According to the draft legislation, any product which the MCA decides is a medicine, would become a medicine. Unless its manufacturer could obtain a medicinal licence for it, it would forcibly be made unavailable to consumers.

Our organisation objects to this proposal on the following grounds:

1. The MCA is a Quango which raises funds for itself from the compulsory licensing of medicinal products. In view of this vested interest it is not in the public's best interests that it should have the sole, statutory power to decide what a licensable medicine is.
2. The new definition of a medicinal product, given in Directive 65/65/EEC, incorporated into UK law since 1995 and which now supersedes that given in the UK's 1968 Medicines Act, allows any substance to be classified as a medicine if it is "administered with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals". This definition is very open to interpretation. The definition previously given in the UK Medicines Act held that a substance was not a medicine unless it was sold with a medicinal claim (e.g. "relieves asthma"). Under the new definition, anything from brandy to coffee, glucose, vitamin pills and culinary herbs could be re-classified as a medicinal product. The MCA would have the power to send its officers, accompanied by police at any time to sweep these products off the shelves and demand that their manufacturers obtain a medicinal licence. Disobedience could result in prosecution and a prison sentence.
3. While such action would seem laughable, there has in fact been an ongoing campaign by civil servants within the Department of Health, to have vitamin products re-classified as licensable pharmaceutical medicines (see *Hansard*, 24th June 1998, speech by former food minister Angela Browning MP). At present vitamin products come under food law because of their inherent lack of toxicity - well demonstrated by decades of safe use. By claiming that *some* members of the public are self-administering vitamin and mineral pills to restore or correct physiological function, it would not be difficult for the MCA to change this situation under the proposed new legislation, thus fulfilling the ambitions of Department of Health Officials.
4. Manufacturers point out that a change to medicinal status for vitamin pills does not mean that a medicinal licence would be *possible* to obtain. Even if the MCA says that a product is a medicine no licence will be granted until the manufacturer has scientifically *proved* that it is a medicine. Since vitamins are not, in fact, medicines but foods, this is notoriously difficult. Cost estimates to attempt it range from £80,000 for a single-ingredient product, to £2,000,000 for a multi-nutrient product. These are completely prohibitive costs for vitamin manufacturers. And there is no simplified procedure. Everything from dangerous cancer chemotherapy drugs to simple vitamin preparations are treated the same under the new EC legislation which Parliament accepted into UK law in 1995.
5. If manufacturers would no longer be permitted to make the products which consumers want, then these products would become unavailable, which is unacceptable to consumers. The costs of appeals against MCA decisions would involve increases in the costs of vitamin products, which is also unacceptable to consumers. Enforced medicinal licensing (if it can be obtained) of a product which is not after all a medicine but a multivitamin, would involve massive increases in the costs of the relevant products, which is also unacceptable to consumers.

The Society for the Promotion of Nutritional Therapy offers the following counter-proposals:

In view of these threats to the continued availability of dietary supplements - threats not merely restricted to the UK but also coming from most member states of the EU - our organisation believes that it is time to afford vitamin products some statutory protection. In the MCA's document *MAL8: A Guide To What Is A Medicinal Product*, clause 5 of the Introduction states that "Products which are clearly foods....come under food safety and food labelling legislation." We would like to see this and all similar documents amended to "foods and vitamins, minerals and herbs sold without medicinal claims and currently (as at 1998) classified as foods by reason of their good safety record....come under food safety and food labelling legislation."

We are most uneasy at the prospect of allowing the MCA the sole right to interpret medicines law with regard to the definition of a medicinal product. We propose that a committee with representatives from the MCA and from interested parties would be a fairer system, and would be less vulnerable to accusations of vested interests.