

RSM 00066

Meeting Report

Health foods or healthy foods

Athens, 22–24 November 1990

Not every topic and problem in the field of public health is easy to categorize. Law, regulation and practice tend to lag behind in their compartmentalization of issues, never quite catching up with society's capacity for change. That is nowhere more true than on the fringes of medicine, characterized by constantly shifting beliefs. Where, to take a concrete matter, do foods end and drugs begin? This meeting in Athens, organized by the World Health Organization and the Athens School of Public Health's Department of Nutrition found impressive backing, notably with support from the European Communities, reflecting the fact that "Health foods" and related products represent an issue worth examining.

There is no standard definition of what is actually meant by "Health foods", though the term seems to be well enough understood; for the purposes of the meeting it was used to cover a wide range of products: whole (unprocessed) foods, organically grown foods, vitamin and mineral supplements, extracts of various naturally occurring products (such as ginseng or garlic) and nutritionally enriched products. What ties this heterogeneous group together is the claim (or the belief, or both) that these are things which are needed in order to maintain a normal state of health – and in some cases thought to create some poorly-defined state of "super-health", marked by longevity, vitality and unbridled energy. They may be sold in normal food outlets, but are commonly marketed primarily through alternative channels ("health stores") which also offer related products falling neither under foods nor under drugs legislation.

In recent years the appearance of these products in the market and their share in it have been continuously growing. The popular press devotes a great deal of space to the subject and the shops specializing in such products are growing in number. Should that be a source of concern? The workshop was held precisely because there is clearly growing concern among scientists and in the public health offices of governments about the proliferation of these products, the indiscriminate use of which could prove hazardous to public health. The workshop, which brought together industrial representatives as well as scientists and officials, was viewed as a first step towards a better description of (and where necessary also regulation of) this market.

That such a fringe "health" market has grown so spectacularly was attributed by one speaker in part to affluence; where basic needs have been met the consumer is left with extra money in the pocket, which may be spent on gilding the lily; at the same time, it was suggested, there was in the affluent society an underlying current of concern, discontent, fear, against which protection is sought. And, as always, there are people who are willing to seek riches by exploiting the health fears of the general public, real or perceived.

Precisely the fact that such products do readily fall between two regulatory stools – neither quite being foods nor drugs – renders the charlatan's task an easy one; products of the type discussed by the workshop can all too readily escape the normal standards which apply to foods and to drugs, as to composition, testing, production and labelling.

The manufacturers of the worst of these products are in some cases marginal firms incapable of survival in either the bona fide foods or drugs markets, and entirely willing to engage in fraud for profit. In its most reprehensible form, their promotional literature may cite evidence and journals unknown to reputable scientists; some of the most seductive reflects hypotheses which once entered the scientific literature only to be later disproved, yet are now lifted out of their historical context and presented as fact. What makes it so difficult for the general public to identify such fraud is the heterogeneity of the market in which it operates; entirely respectable calcium supplements with responsible labelling and official approval as drugs can stand side by side with products which represent no more than misunderstood folk medicine or plain flights of a producer's fancy, sometimes backed by the injudicious statements of individual health professionals. The field is also characterized by a range of foods claiming for very mixed reasons to be healthful when used – the one as a product of organic farming, the other by virtue of its fortification with supplements or its adherence to a particular dietary school; such food is generally highly priced, for reasons which are sometimes justified (organic farming) but which in other cases seem to represent mere commercial opportunism.

A Belgian survey showed the extent of the phenomenon; 40% of the population studied had used unrecognized products for headache or migraine, 24% against vague complaints such as “joint and muscle pain”. There were large differences between groups, however, with women being more frequent users than men, young people more than old, and use in cities higher than in rural areas. In general the users were relatively well educated; scepticism towards allopathic medicine (“ordinary” medicine) was no more prominent among users than in the group that did not use these products. From its computerized list of products on the “health market” the Belgian Consumer Organization (BEUC) took 271 for study; of these, half were found to be clearly useless. Remarkably, when asked how they came to use “health products”, 36% cited the advice of their General Practitioner; of the categories of products recommended by the General Practitioner; of the categories of products recommended by the General Practitioner, 70% were of the “useful” category yet 28% were in the category of useless products. Clearly, there is a complacency within the medical profession towards these products. The same would seem to apply in some countries to the pharmaceutical profession; in Belgium not only 99% of the useful products but also 75% of the useless products were sold through pharmacies. The same study provided hard data on the capacity of the user for deceit or self-deceit; even for useless products, 57% of the users reported positive results, and 77% were generally satisfied with the product; 45% had recommended such a product to others. The average period of use was strikingly long – 22 months for useless products versus 45 months for useful products. In all \$60 per person per year was being spent on health products, \$38 of it for products categorized as “useless”.

Regulation has tended to affect this field only insofar as the products have been submitted to and approved by the bodies handling drug regulation, yet even as regards vitamins and supplements the scope and interpretation of the existing rule can differ. Beyond that, the authorities have tended to enter the field only where problems of toxicity emerge (e.g. in recent cases involving germanium, tryptophan or aphrodisiacs based on lead) and occasionally (as in the U.S.A.) where a food product such as oat bran cereals makes indefensible claims to promote health. In principle, however some of the basic notions in drug regulation (notably those relating to quality, safety, efficacy and truth) can be applied in this borderline area as well, the essential question being how much scope one is prepared to leave for the unproven. One notion is to allow some leeway to “novel products” reflecting current scientific hypotheses even if there is no certainty as to their value. What is evident is that if there are regulations they need to be actively applied; few European agencies, with their

limited resources, have been as effective as the United States F.D.A. at the gargantuan task of tracking down and suppressing the sort of prophylactic or therapeutic claims which would bring a product under the aegis of drug law. Currently, indeed, new regulations to forbid health claims for foods and supplements are under preparation in the USA, a proposed text having reached the Federal Register in July 1990.

As might have been expected, the meeting ran into a conflict when considering the manufacturers' point of view, particularly as regards the principle of "freedom of choice" in such matters; as some speakers argued, "freedom of choice" is sometimes no more than a euphemism for "freedom to deceive". People were more inclined to allow for freedom of "informed choice", where the onus of providing information would lie with the manufacturers. Such information would above all have to be complete, as deception will often lie in the omission of essential facts. The "European Federation of Health Products Manufacturers" was at all events able to demonstrate that its 105 member companies have their standards. There were, alas, also firms outside the Federation ("the cowboys") who would stop at nothing to sell their products and take maximum advantage of consumers' trust. The ability of such an Association to promulgate standards is clearly an asset, known from the related case of the European Proprietary Association whose members manufacture over-the-counter medicines; its limitations lie in part in the impossibility of imposing real sanctions, particularly on non-members.

It is indeed tempting to argue that the entire solution to the problems lies in information rather than in law, but past attempts to give the public reliable information on what constitutes good health practices have sometimes stranded on meaningless generalities and negative advice ("do not smoke", "eat less salt", "do not become obese" ...). Where public information becomes more precise it is often perceived as too complicated (who knows what polyunsaturated fatty acids are?). Such well meant attempts at educating the public are all too often less appetizing than the bold promises made for health products, offering a direct road to good health or some state of supposed super-health.

So what might a meeting like that in Athens be expected to achieve? Within the confines of three days it achieved a great deal.

The meeting was clearly concerned about the health products phenomenon, whatever faces it might have, and it indeed put the problem of information squarely in the forefront of its approach, while being well aware of the practical problems involved. The public, it declared, should be helped to develop a more critical attitude towards statements and inferences being made about such products. People should learn to ask critical questions too about safety requirements and proper dosage. The responsibility for creating such a state of critical awareness, participants believed, lay with the professional organizations, consumer organizations and the media, who should take their duty seriously. To that end, the medical and health professions should themselves be better educated and informed about the potential risks and uses of health food products and about the real need (or lack of need) for dietary supplements; they should also be better educated in nutrition generally.

As far as freedom of information and action went, the meeting believed that the consumer's right of choice must be preserved, but was equally emphatic that this did not bring with it a right of salespeople to vend useless products with the help of unsubstantiated claims. A general regulation to cover claims for dietary supplements should be based on the rule that if a statement is misleading it shall be deemed illegal – even if it is literally true. Labels would have to provide details of ingredients, composition, the amounts recommended (set where necessary alongside the accepted "Recommended dietary allowance"). There should be proper instructions for use and a statement of any limitations which need to be respected. Complementary to these requirements would be a rule that whereas manufacturers

are free to distribute leaflets, magazines and books dealing with generic products it should not be permissible to use branded product names in such material. Furthermore, publication of an accepted “positive list” of substances known to be of nutritional significance would help to prevent consumers being misled.

This is of course a field in which sales messages are often routed through devious channels; the consumer is often not aware of the commercial nature of the information which reaches him. Hence some of the meeting’s further conclusions: advertisements should not be published (as they commonly are) alongside associated editorial material promoting the merits of the product concerned – or its components. There should be no use in packaging materials and inserts of “testimonials” – a form of advocacy which was largely eliminated from the drugs field many years ago. One must make a firm stance against inferred claims, which can be as persuasive as explicit ones; and clear claims to maintain health and vitality should be allowed only where they are clearly proven.

Beyond information, the meeting also looked at the broader aspects of regulation called for in the public interest. In its simplest form, official involvement merely means ensuring that the authorities know what is on sale, i.e. manufacturers have to notify their products to the authorities; that is for example the situation of all foods in Greece, of dietary supplements in Belgium, and of “novel foods” in the United Kingdom. The meeting wanted to see such a practice enforced for all dietary supplements, ensuring too that the authorities know precisely what these products contain, so that if any ingredient subsequently proves to be harmful proper action can be taken.

How much further than this – coupled to improved information standards – regulation needs to go is a vexed question. No-one appears to be a very firm proponent of applying drug regulation in its full rigour except where products venture clearly into the pharmaceutical field by virtue of their composition or their labelling (i.e. where there are claims to prevent, alleviate or cure an illness). One interesting middle road was suggested by the meeting. According to this a manufacturer or importer of a “health product” would be required, not only to notify his product to the authorities, but also to maintain at his premises a full file on it, open to public or official examination. This would include:

- the composition of the product as currently manufactured and a record of any composition employed earlier (with batch numbers indicating the point at which the composition was amended);
- copies of any promotional literature of materials distributed by the manufacturer for the product;
- details of the purity criteria applied;
- a summary of the grounds on which the composition has been chosen;
- a complete collection (with a summary) of published literature indicating the suitability and safety of the components for the purposes for which the product is most likely to be used.

With ready access to such a file, consumer organizations would be better placed to carry out their defensive task; official bodies could call for additional information where necessary, e.g. if a health risk is suspected.

Recommendations like these from the Athens meeting could, if they are promptly followed up, do a great deal to make the “health market” healthier. The fact remains, however, as the meeting noted, that in this sometimes misty field one often encounters a need for more and better research if one is to determine where truth – and safety – lie.

*Elisabet Helsing
Copenhagen, Denmark
Antonia Trichopoulou
Athens, Greece*

December 1990