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Disorder in the medicine cabinet

FRA REDAKTØREN

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Pharmaceuticals need not cure anything at all, and undocumented dietary supplements are permitted to pose as medical drugs. Norwegian consumers and patients are the losers.



Photo: Einar Nilsen

According to the Ebers papyrus that dates from around 1500 BCE, a medical drug must contain three components: an active ingredient, a binding agent and some palatable substances (1). The ancient Egyptians were scrupulous. Nowadays, we are not so fussy. According to Norwegian authorities, drugs are products ‘that can be used to prevent or cure illness, or are claimed to have such effects’ (emphasis added) (2). Thus, according to the prevailing regulations, a drug may not necessarily contain an active ingredient at all – or have any kind of physiological effect, for that matter.

We may thus keep ourselves with governmentally approved drugs that are proven to cure nothing at all, such as ‘homeopathic drugs’ (3). In addition, we have an entire array of drug classes that may or may not contain any active ingredients. For example, ‘plant-based drugs in well-established use’ require no clinical trials, only that they (or a similar drug) have been in well-established medical use for at least ten years, that they have a ‘recognised effect’ and that they are sufficiently safe (2). Nor are any rigorous effect studies required for ‘traditional plant-based remedies’, only that the manufacturer can point to 30 years of safe use. ‘Natural remedies’, on the other hand, are required to contain an active ingredient (!), but it must be of ‘natural origin’ and not ‘unduly processed’ (2, 3). If the remedy in question has been in use for more than 30 years, no clinical, pharmacological or toxicological documentation is required (2, 3).

If this seems confusing, it does not help that dietary supplements, whose dividing line with plant-based drugs is often quite blurred, are *not* classified as drugs. Dietary supplements are regulated by a separate set of rules, which determine that these are ‘concentrated sources of vitamins or minerals or other substances with a nutritional or physiological effect’ (4). In

other words: drugs, which do not need to have any physiological effect, are approved and controlled by Medicines Norway, while dietary supplements, which by definition have a physiological effect, are controlled by the Norwegian Food Authority and need no approval by any official body (4). In addition, dietary supplements can be marketed freely, as long as the manufacturer does not 'claim or give the impression that the product prevents, cures or alleviates illness' (4).

While conventional pharmaceutical drugs are subject to extremely strict rules for their marketing, the sale of dietary supplements directly to consumers appears to be a virtual free-for-all. Using statements from happy patients, pseudo-scientific terms, 'facts boxes' and pictures of 'researchers' in white lab coats, such products are completely oversold without any clinical documentation whatsoever. The target group is often vulnerable. Among them are people who suffer from or are anxious about severe brain disorders (5, 6), unrestrained by the fact that no serious studies have demonstrated any effect of dietary supplements on dementia or cognitive impairment (7). Nor are natural remedies without problems in this respect, although their claims are less bold.

There can be little doubt that this thicket of rules produces unfortunate consequences. It is bad enough that everything from pure fraud to possibly effective, but undocumented drug treatment are muddled together in largely incomprehensible governmental regulations. It is even worse that documentation of the negative health effects of many of the concoctions in question is gradually emerging. A 22-year follow-up study of more than 38 000 American women showed increased mortality among those who used dietary supplements (8). A Cochrane review showed that supplements of many antioxidants, such as beta-carotene, vitamin E and vitamin A, are associated with increased mortality (9). In a recent, large cohort study of patients with curable cancer, the use of complementary medicine (including various forms of dietary supplements) was associated with a higher risk of death and less use of conventional therapy (10). In a recent Norwegian study, 23 % of the dietary supplements included in the analysis contained various doping substances, drugs and/or illegal amounts of caffeine (11). The manufacturers may brazenly and with impunity disregard such facts when the products are marketed – often quite aggressively – directly to consumers.

When we resort to pills, powders and potions we are patients, or regard ourselves as potential patients, and we are more vulnerable than when we are in our role as normal consumers. The Norwegian market for non-conventional drugs and dietary supplements is thoroughly regulated, but in a way that conceals the difference between effective and ineffective, documented and undocumented, true and false. This is a source of confusion, rather than of clarity and help. It paves the way for improper and unethical marketing by unscrupulous operators, with potentially negative effects on public health. The Norwegian medicine cabinet needs a good cleanout.

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