

Herbals: Can Food Really be Medicine?

“Food is medicine” is the dogma of many traditional herbal medicinal systems. This is paradoxically turned into its exact opposite in Europe: legally, foods can never be medicines, no matter what the body of scientific evidence may claim.

by Irene Wohlfahrt

The use of plants for the treatment of various ailments is as old as humanity itself. In fact, there is plenty of evidence indicating that other animal species besides humans make use of the various health effects afforded by plants and herbs.

Before the advent of synthetic actives, herbal medicine was synonymous with medicine. An old German adage states that “for every illness, an herb sprouts,” but traditional medicine often is more than just phytotherapy. The World Health Organization defines traditional medicines as: “the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health

as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.”

Among the many traditional medicines are Ayurveda, Siddha medicine, Unani, ancient Iranian medicine, Irani, Islamic medicine, traditional Chinese medicine, traditional Korean medicine, acupuncture, Muti, Ifá, and traditional African medicine.

Regulatory Background

Throughout Europe, legislation for medicinal products, including phyto-medicines, is not completely harmonized. Some areas are covered by EU Regulations, which are binding for all Member States, and other areas, by EU Directives, which are adapted into national law as

the member states see fit, resulting in varying interpretations of the Directives.

Botanical products can belong in one of the following drug categories: new herbal medicinal drug, well-established used drug (WEU), traditional herbal medicinal product (THMP), or one of the niche categories (e.g. orphan drug). Also, categories such as homeopathics, anthroposophical therapy, or medical device are open to botanicals. Then, of course, there are food supplements and other food categories, which will only be covered in passing in this article.

THMP is the most important category for botanicals with a tradition of use of at least 30 years (15 of which must have been in the EU). Regulated by the THMP EU Directive 2004/24/EC, these products were granted a simplified registration procedure rather than a full drug authorization, on the grounds that safety and efficacy is already proven by their tradition.

The THMP category is open to botanicals only - not to isolated active compounds. Vitamins/minerals can only be included if they were part of the traditional product. In keeping with the traditional aspect, only self-diagnosable indications can be treated by THMPs, i.e. indications whose diagnosis would require medical specialty equipment or knowledge are not covered by this directive. Also, THMPs can only be non-prescription drugs applied orally, topically, or by inhalation.

Beyond THMP

THMP is not the only category open to medicinal plants, however. Market data show that botanicals globally are increasingly incorporated into food categories, most notably food supplements. Of the \$35.8 billion spent on herbals in 2014, 60% was spent on dietary supplements.

The top growth regions are India, China, Japan, Malaysia, and South Korea, while the top sales regions are Asia Pacific and North America. Ginseng was the highest grossing single ingredient, while combination products sold more than double the amount of ginseng. In Europe, the botanical market is dominated by Germany and France, whose combined market shares almost equal half of the entire EU market (27% and 22%, respectively).

However, the regulatory situation of botanicals currently discourages their use in food categories, since no health claims for botanicals have been authorized. Consequently, herbal medicinal products in the OTC sector, of which THMP is a sub-category, are growing again after taking a hit due to the loss of reimburse-



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ment in 2004.

Phytotherapy Platforms

Research in phytotherapy has led to the identification of a small but significant number of single active substances that were later developed into new chemical entities. A famous example is acetyl-salicylic acid, which is a derivative of a substance originally

discovered in willow bark, salicylic acid. From 1980 through 2006, approximately 70% of all new chemical entities were discovered during research on natural products.

But apart from supplying the pharmaceutical industry with precursors, phytomedicines have grown into their own during the past decades, mostly due to the fact that they

are generally believed to have fewer side effects than synthetic substances.

Benefit Platforms

One of most prevalent indications for phytomedicines is cough and cold. This is not surprising, considering the fact that cough and cold affects practically everyone at least once per year. The symp-

toms are very easy to diagnose and unpleasant enough to drive those affected to seek relief fast. Botanicals used for cough and cold THMP, either singly or in combination, are pelargonium, sage, thyme, echinacea, melissa, peppermint, and ivy.

For herbal medicinal products, cardiovascular health also is an important indication. *Crataegus* and Horse chestnut are the main botanicals in this indication, with garlic playing an important part as well.

Third in place is gut health, most notably digestion and stomach disorders. Peppermint is a leading traditional herb in this indication, either as a tea, or as an essential oil. Also traditionally used are fennel and cumin.

The next important indication is mental stress and mood disorders, on the rise due to the increasing pressures exerted by the modern lifestyle. Valerian and St. John's wort, are the leading botanicals in this indication.

Comparing the EU and US botanical markets, the same botanicals appear in the top 10 in both regions. Ginkgo biloba, well known for its effects on cognition and memory, is the top-selling botanical in Europe and in 10th place in the US, while cranberry leads the pack in the US but does not appear in the EU charts at all. Other botanicals both regions have in common are St. John's wort ginseng, saw palmetto, echinacea, garlic and milk thistle.

Food or Drug?

Many medicinal plants such as valerian, chamomile, peppermint, and ginkgo - the list goes on - have a long tradition in their respective indications and are thus very thoroughly investigated. Many phytomedicines also have doubled as kitchen herbs for a long time, most often as spices or preservatives, due to their antimicrobial or digestive action, effectively blurring the demarcation line between food and

drug. And conversely, some plants or plant parts have had a long history of food use before their medicinal properties were discovered.

The respective medicinal benefits, pharmacological dosages, and known active compounds of the botanicals are described in the various monographs (Commission E, WHO, ESCOP). Generally, a plant that has uses both as a food and as a drug, e.g. garlic, is considered a food as long as the effective daily dosage (i.e. the pharmacological dosage) is not reached. By definition, the plant then has no pharmacological action. For garlic, the pharmacological dosage is 4g of fresh bulbs or equivalent preparations per day, at which dosage the plant becomes effective at reducing elevated lipids in blood, according to its Commission E monograph.

Does that mean that, by buying more than 4g of garlic in a supermarket, the consumer is, in effect, buying a drug? The obvious answer is no - medicinal drugs, while not monocomponent, chemically distinct substances, are still standardized for their active principles, have under-

gone safety and efficacy trials, and have been authorized for sale as drugs, none of which applies to the garlic found in supermarkets.

Also, herbal drugs usually contain herbal extracts rather than dried plant parts, since reaching the effective dosage through food use can be a daunting proposition. This is especially so if, to stick to the example, one does not like eating 4g of garlic per day.

Can Food be “Medicine”?

Nevertheless, the question opens up an interesting area for discussion. Foods cannot claim to prevent or cure any disease, according to the current legal mindset - their label claims cannot allude to diseases at all. Still, eating an orange or other fruit rich in vitamin C a day will prevent scurvy.

Eating 4 grams of garlic per day will keep your cholesterol down, thus preventing arteriosclerosis. Another example is cinnamon, whose blood sugar lowering properties were only recently discovered, or the aforementioned garlic, which was considered a mere spice for the longest time.

In fact, normal foods are being discovered as having medical properties almost weekly. In a way, it can be argued that the legal requirement for a food - not preventing diseases - is patently not fulfilled for these botanicals (and for many others).

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Future Perspectives

A higher level of evidence affords better IP protection and added value. For botanicals, the trend away from food supplements and towards herbal medicines supports these higher product values in Europe, where the number

of new THMP registrations is increasing.

This is at least partly due to the regulatory situation, which currently does not allow botanical food supplements to make any health claims whatsoever. The reverse was the case when the THMP regulation came into force in 2011. Then many phytomedicines were either converted to herbal supplements around this time, or their drug authorizations were allowed to lapse completely. Now, however, there is a definite switch back to herbal medicinal drugs. The THMP regulation, designed as an easier route to market registration for traditional herbals, is generally considered to be a step in the right direction as far as harmonization across Europe is concerned. However, because of the requirements of history of use, this regulation does not take innovative herbal medicinal products into account - they have to undergo a complete drug authorization procedure, just like any synthetic drug.

Getting Authorization

Drug authorizations, however, hinge upon two things: the existence of an active principle, and of a mechanism of action that can be clearly demonstrated, ideally in a dose-dependent manner. For herbal drugs, however, e.g. Ginkgo biloba, Panax ginseng, or *Valeriana officinalis*, no single active principle has ever been identified, nor is the mode of action identifiable. Usually, a group of substances is suspected of being the “active principle,” and the very efficacy of most plant-based medicines stems from a group of actives working synergistically, which makes identifying the mode of action a tough proposition.

This, of course, implies a discouraging array of safety and efficacy testing, in order to gather all the information required for a full Common Technical Document (CTD), which is the basis for a drug

authorization. In other words, new herbal drugs are extremely hard and costly to get into the market, which is why the rate of approval of new drugs has declined during the last 20 years or so.

Suggestions have been made towards changing the regulatory environment in such a way that innovation in herbal medicinal products is facilitated, e.g. by allowing a hybrid authorization for traditional herbal medicinal products with a certain grade of innovation (Minghetti et al, 2016). This might include a possible simplification in terms of characterization, pre-clinical studies, and clinical trials in case there is already evidence for a plant’s use, even when the intended purpose lies in another indication.

The Alternative Argument

Outside the EU, many countries have a category in place called “alternative medicines” or an equivalent, which houses mostly multicomponent products that have medicinal qualities - in most cases, medicinal plants and traditional remedies. Installing such a category in Europe would remove not only the current damper on innovation caused by the NHCR but also the confusion caused by the somewhat artificial food-drug demarcation without threatening the sovereignty of synthetic monocomponent drugs.

Without such an approach, innovation in herbal medicines is likely to stall completely, until such time as a decision has been reached on how to tackle the issue of health claims for botanicals. But even this would only have an impact on the food industry, albeit a huge one. New herbal drug development would still face its own issues that only a paradigm shift in the regulatory environment could resolve. ▼

Irene Wohlfahrt, MSc works at the consultancy firm analyze & realize GmbH in Germany.

SOURCE: INNOVAMARKET INSIGHTS



› *Nature's Way Premium Extract Valerian Dietary Supplement (Australia). "Naturally promotes restful sleep without the side effects commonly associated with sleep aids. Supports restful sleep."*