



## Regulations influence on the future of botanicals

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*Botanicals are yet again under the microscope. **Loren Israelsen** explains why regulations for botanicals are being re-evaluated for the functional foods market.*

There was a time, not long ago, when the botanical industries of Europe, U.S. and Japan (and pretty much everyone else) lived in blissful isolation of each other's law and regulations. Like evolution, each market had, for better or worse, crafted a domestic scheme to regulate botanical products, either as drugs, traditional medicines or dietary supplements. International trade in herbs was largely found on the spice and seasoning shelf at your local grocers. Since the late 1980's, all of this has changed. Domestic herbal markets have become a bazaar of international offerings ranging from the classic dosage forms (capsule, tablet, drops) to an astonishing array of beverages, snacks, bars, gels, teas, sprays as well as pills. Sadly, this trend is now pushing into soups, chips, breakfast cereals and other well-known conventional food forms.

Claims for this growing sector, once timid in most markets, have blossomed into a range of claims including explicit drug and traditional medicine claims, structure/function claims as well as general health benefit claims. Regulators, alarmed by the sudden expansion in the number of new claims and delivery forms for botanicals, have responded with new regulatory schemes to bring definition and control to the sale and marketing of botanicals.

In the past two years, Japan, South Africa, Canada, Mexico, Brazil, Thailand and other countries have either launched major new regulations for botanicals or have begun to do so. Key markets of the E.U., the U.S. and Japan are increasingly influencing each other's botanical regulations in search of new markets. What were once fairly predictable and well-established markets have transformed into volatile, confused, if not interesting new markets.

### **BOTANICALS AS DIETARY SUPPLEMENTS**

The Dietary Supplement Health and Education Act of 1994 (DSHEA) was a landmark shift in US policy by recognising botanicals as dietary supplements, a class of foods. This policy is based on a "right-to-consumer-access" philosophy

and requires a mature distribution and retailing infrastructure as well as an active and interested popular press. It also requires industry self-regulation and informed consumers. The explosive post-DSHEA growth of the botanical market was in large measure occasioned by the dramatic expansion of key and well-researched botanical extracts, specifically, ginkgo, St. John's wort, echinacea and, to a lesser degree, kava. The key elements mentioned above worked to perfection, and the popular press extolled the virtues of these natural "medicines" to millions of forgetful, depressed or immune-deficient consumers. This explosion in demand resulted in severe shortages of key raw materials and, sadly, left consumers with uncertain quality and, over time, confused expectations. Today, sales of these and other key botanicals have fallen sharply and suggest a fundamental need to engage health care professionals, trade associations and the government to re-establish the value and quality of botanicals in the minds of consumers. There is now growing interest in considering a traditional medicines category to allow some type of government stamp of approval, which many believe is the key to restoring consumer confidence in botanical dietary supplements.

### **BOTANICALS AS DRUGS**

Germany, France and Australia have led the way in regulating botanicals as prescribed, registered or licensed medicines. This has, in the case of Germany and France, led to major research and development advances and has given the world Ginkgo biloba, St. John's wort, saw palmetto, black cohosh and other well-researched botanicals. The key drivers under this model are government reimbursement, physician and pharmacist recommendations, and the willingness by regulators to recognise and evaluate botanicals as medicines. In recent years, the intense economic pressures to reduce government budgets have resulted in substantial loss of reimbursement for key botanicals along with growing pressure from major retailers to be allowed to market botanicals under an OTC or free sale environment.

### **BOTANICALS AS TRADITIONAL MEDICINES**

In China and India (as well as England, Germany, France and Japan), botanicals are recognised as some form of traditional medicine in whole or part. Traditional medicine is largely a cultural perspective and embraces local traditions and customs of use. A number of countries are increasingly interested in a traditional medicines class (the US among them), as it creates a relatively inexpensive way to create a recognised and regulated class of medicines that are not held to the extraordinary expense of new drug review processes.

### **BOTANICALS AS FOOD INGREDIENTS**

In view of the continued sluggish growth in the conventional foods industry and the rather sudden decline in botanical dietary supplement sales, these two former strangers have found good reason to cooperate. In the year 2000, there were 1,271 new beverage introductions in the U.S. alone. (*Prepared Foods, April 2001*)

"Herbal and fortified drinks—a big newsmaker for the last couple of years—made even bigger headlines this year with the introduction of Spire from Procter &

Gamble...Other significant herbally fortified drinks were launched by Snapple (Cadbury Schweppes), SoBe (PepsiCo) and Mystic Zotics." (*Prepared Foods, April 2001*)

These launches were in part a response to the astonishing success of Red Bull, which has taken the U.S. and European markets by storm. One cannot help but remember the introduction of a new drink in 1886 called "Coca Cola" which contained extracts from cola nut and coca leaves and advertised itself as an "esteemed brain tonic and intellectual beverage." Indeed, everything old is new again. Major countries have expressed concern and alarm at the dramatic increase in the addition of non-generally recognised as safe herbal ingredients in conventional foods. The U.S. Food and Drug Administration has recently sent strong correspondence to the food and botanical industries warning against this practice, as such herbal ingredients would be regarded as unapproved food additives when not sold as dietary supplements.

## **SUCCESS AND FAILURE**

In the fast-changing world of botanicals, there have been clear winners and losers, although success and failure must be seen in perspective, as many markets are going through significant commercial, regulatory and social change, which makes long-term success and failure difficult to predict. Notwithstanding, some trends have become apparent.

## **FILLING THE LIFESTYLE GAPS**

Soya (a botanical) and green tea fit the profile of botanicals that fill a lifestyle and health niche. Both products are well recognised and understood by consumers worldwide, are traded as commodities and hence are inexpensive in the raw material forms, and have well demonstrated health benefits when used on a regular basis. In short, this is a "feel good" dietary addition for most households. Economic success will in part be determined by sheer volume and quantity of sale. Dietary supplements, almost by definition, are viewed and taken as adjuncts to the diet, and consumers have shown a willingness to take only so many pills per day. Soya, green tea and similar products that enjoy the advantage of being generally recognised as safe, may be added to foods with fewer limitations and can be added to a host of food products.

## **FILLING THE THERAPEUTIC GAPS**

The other trends for success will be recognising and filling therapeutic gaps in product categories important to consumers, particularly middle aged females. Saw palmetto extract for BPH, black cohosh for menopausal symptoms, valerian and hops for insomnia, are good examples of products which provide new and useful benefits in very large categories that are underserved by synthetic pharmaceuticals. However, these products, when sold in low regulation markets, tend to become lost in a sea of inexpensive competitors (many of which improperly borrow science from leading researched products), thus confusing consumers. The future success of these products will depend on raising them out of "general health product perceptions" to a higher state of respectability and professional recommendations.

## WHAT IS THE FUTURE?

It would appear that in many domestic markets the grass is greener somewhere else. In the free open market, there is interest in considering more disciplined and regulated models to bring order and consumer confidence into the market. In highly regulated markets, which lack the excitement and free-wheeling nature of free markets, there is a yearning for access to new retailers, lower price points and more and exciting popular press. It is likely that the general regulatory trend will be a parallel track of seeking openness in closed markets as well as discipline and higher regulatory categories in open markets. This would seem both logical and practical for most countries, depending on their respective regulatory situation. One thing is certain. There will be no lack of excitement in the worldwide botanicals market for years to come.

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