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Booker, A. and Heinrich, M.

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VALUE CHAINS OF BOTANICALS AND HERBAL MEDICINAL PRODUCTS: A European Perspective

By Anthony Booker, PhD,^{1,2} and Michael Heinrich, Dr. rer. nat. habil.¹

¹ Research Cluster Biodiversity and Medicines/Centre for Pharmacognosy and Phytotherapy, University College London (UCL) School of Pharmacy, University of London

² Division of Herbal and East Asian Medicine, Department of Life Sciences, University of Westminster, London

Introduction

In recent years, the quality of botanicals has come under increased scrutiny. Despite the availability of numerous high-quality products from reputable companies, health care professionals, patients, and consumers are understandably concerned about questionable botanical ingredients in various consumer products. In Europe, this includes products that are generally unlicensed and unregistered supplements (also referred to as “botanicals”), which are often poorly regulated, or even totally unregulated, depending on the country of jurisdiction.*

This overview discusses the concept of value chains (some have referred to them as “value networks”²), emphasizing that it offers a framework for assessing the current quality problems with botanical raw materials and extracts with respect to their adulteration, and for developing strategies for best practices in the global botanical industry. We propose that some form of self-regulation, if it enforces good quality and follows best practices, will need to be linked to an understanding of value chains by those selling final products, irrespective of their regulatory status. Importantly, the concept of value chains also involves an understanding of the socioeconomic impact of different production systems on primary producers and other stakeholders.

The examples discussed here are based on studies of plant-based products sold in Europe (and, to a lesser degree, in North America) and compares regulated products with unregulated products, since such distinctions apply in Europe, per below.

The Need for Value Chains

An important difference between, for example, the United States and member states of the European Union (EU) is the level of regulation of plant-based products and the subsequent enforcement of the regulations. The European system offers an example of how quality assurance was introduced over the last 15 years. In the EU, traditional herbal registration (THR), as established by EU Directive 2004/24/EC,³ has set minimum standards that aspire to guarantee the quality and safety of herbal medicinal products sold with medical claims for minor self-limiting diseases. The THR

is one of several regulatory frameworks, and many European countries also regulate products under the Well-Established Use Directive⁴ (Article 10(a) of EU Directive 2001/83/EC, as amended) or under national regulations that allow for full licensing as medicines.

THR is an example that highlights how consistent and high-quality herbal medicines can be produced by using such a regulatory framework. Alternatively, a company could go for a more rigorous and well-enforced self-regulation, driven by the relevant industry bodies. The introduction of more rigorous standards implemented at a global level results in a greater integration between some processors and primary producers, who are then able to ascertain better quality and to obtain more stable prices. Such standards could be based on a regulatory framework or on commonly agreed-upon principles of best practice, which are certified, for example, by an external agency.

A useful framework to achieve this improved quality is the concept of value chains, which for certain key food products (e.g., coffee [*Coffea arabica*, Rubiaceae], tea [*Camellia sinensis*, Theaceae], and cocoa [*Theobroma cacao*, Malvaceae]) have been investigated widely. However, value chains of medicinal botanicals have been largely ignored in the global research literature.^{5,6} Analysis of the value chains of botanicals is important, since it is a critical part of understanding the quality and safety breakdowns that can occur

*The American Botanical Council (ABC) has been actively bringing together stakeholders interested in educational efforts intended to help reduce the level of adulteration and contamination of ingredients used in such products.¹



along the chain — breakdowns that are likely to result in sub-standard or even unsafe finished products for consumers. While this is in no way a new problem (in fact, pharmacognosy as a scientific discipline has resulted, at least partially, from the need to identify adulteration and define best quality), it has become an evermore relevant problem with the rapid and dramatic globalization of trade in botanicals and herbal medicinal products.

A value chain differs conceptually from a supply or commodity chain in that it is founded upon the insight that any company is more than a random assembly of machinery, people, and finance. Only if these things are arranged into definable systems will it become possible to produce a higher quality commodity for which customers are willing to pay.⁷

In our own research on botanicals and regulated phyto-medicines, we have found that value addition can be introduced at various stages of production. This can occur, for example, through certified organic cultivation, use of superior extraction techniques, and/or through more stringent regulation, such as the European THR.⁸⁻¹⁰

For example, in the case of saw palmetto (*Serenoa repens*, Arecaceae) berry we found that regulated products manufactured using an extraction process with a soft gelatin capsule dosage form were typically of higher quality and more consistent than other products tested.¹¹ In the case of *Rhodiola rosea* (Crassulaceae) root products, we found that approximately one quarter of products that were marketed without a THR were of poorer phytochemical quality than those marketed with a THR as Traditional Herbal Medicines (THMs).¹⁰ In addition, some of these products were adulterated with other species or did not meet their label specifications. This does not mean that all non-THR products were of poor quality. In fact, some sold as botanicals were comparable. One major problem with non-THR products is that it is practically impossible for consumers to differentiate high-quality products from low-quality products. Our data confirm that by choosing a THR product, the quality and safety are assured.

Benefits of Vertical Integration

We suggest that vertical integration, in which contracts are made directly with the farmers and primary processors, not only benefits those involved in primary production but also can lead to higher quality products for consumption in more economically developed countries. In such a value chain, a lead organization is responsible for two or more intertwined steps of the manufacturing or value chain process. Vertical integration, however, has been criticized as resulting in a high

degree of dependence on the primary producers.⁹

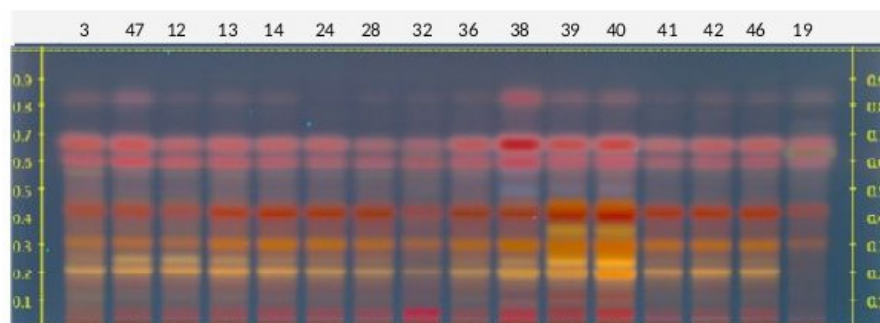
The product quality and economic benefits for a primary producer are highlighted in our work on turmeric (*Curcuma longa*, Zingiberaceae).¹² Looking at the production process of a multipurpose product containing turmeric root and rhizome, we found that turmeric derived from organically grown crops in India under contract from a European manufacturer retained more volatile phytochemical compounds. Such compounds are generally lost when turmeric is stored for long periods (e.g., when the market price is low). Moreover, we found that some products that were obtained through middlemen were the wrong species and thus did not meet the label claims (Figure 1).

Products derived from a vertically integrated value chain (VIVC) have obvious benefits for the consumer and, based on our assessment, the producers as well. The producers we evaluated in India, who were able to access the international market and agree to a quantity and price with the manufacturer prior to cultivation, were less susceptible to the price fluctuations and market shocks that can easily upset the smooth and expedient transfer of goods from one country to another.¹²

Value chains of botanicals and herbal medicinal products can be highly diverse. Vertical integration is not widespread throughout the industry, and free markets and middlemen are still the most common routes of supply. Supply chains for cultivated materials and wild-collected materials each have associated challenges, and the picture is further complicated by a lack of regulatory harmonization among different global regions and countries, including many that are within the EU.

In our own investigations,¹⁰⁻¹² we found that a VIVC was conducive to the manufacture of organically grown products in which it is a requirement that traceability to the exact area of origin can be proved, and documented procedures for any primary processing are implemented (Figure 2).

Figure 1. HPTLC Chromatogram of Various Turmeric Root/Rhizome Samples and Powdered Products



More phytochemicals were present in the fresh rhizome samples 38, 39, and 40. The integrated chain powder samples 47, 12, and 13 displayed a strong zone at Rf 0.25, which was also observed for the fresh rhizome samples. The integrated chain samples and the fresh rhizome samples also displayed a stronger zone at Rf 0.83. Sample 19 displayed a different pattern, and the bisdemethoxycurcumin zone at Rf 0.2 was missing, which indicates that this sample was not *Curcuma longa*.



A



B



C



D

THR vs. Non-THR Products

Multiple factors differentiate products produced with a THR. Although there is no requirement for a THR product to be linked to any particular value chain, a company's commitment to and considerable financial investment in obtaining a THR constitutes a significant value addition to the product (Table 1), and it requires the establishment of robust systems of quality control, from good agricultural and collection practices (GACPS) to good manufacturing practices (GMPs) throughout the value chain.

THR products used to treat minor self-limiting conditions are now widely available within the EU. It is a legal requirement for any product that makes a medicinal claim, or any product that is deemed to have a significant pharmacological effect, to hold a registration before being placed on the market.¹³ Such products can be readily identified by their unique THR number, and many also display the THR logo.



Food supplements (botanicals), however, are not yet required to have a THR before entering the market in Europe, and they remain widely unmonitored. Although regulations do exist, they are rarely cited or enforced. Food supplements are often mislabeled or make misleading claims, and the lack of effective enforcement in Europe has resulted in a large number of these products entering the market.

The value chains of food supplements typically are undisclosed, and it is only through careful analysis of the products that problems may be detected. In our unpublished investigation of milk thistle (*Silybum marianum*, Asteraceae) fruit extract and our analysis of ginkgo (*Ginkgo biloba*, Ginkgoaceae) leaf extract products,¹⁴ carried out in collaboration with the BBC for its series *Trust Me, I'm a Doctor*,¹⁵ we found widespread quality and adulteration problems. Approximately 40% of unregistered milk thistle products, sold legally as supplements in the EU, contained very low levels of the bioactive marker compounds collectively referred to as silymarin. Furthermore, after a detailed investigation, we found that more than 50% of ginkgo products either were not compliant with their label claims; contained high levels of flavonols, rutin, and/or quercetin; or were adulterated, one with a 5-hydroxytryptophan (5-HTP) derivative.

Wild-collected vs. Cultivated Material

The impact that different value chains have on botanicals and herbal medicinal products and their quality also can be linked to livelihoods and sustainability. Many rural communities and indigenous groups, particularly in Asia, depend

Figure 2. Cultivation and Primary Processing of Phytomedicines in an Integrated Chain

Photo A: Medicinal plants are harvested and put through a tiered wash cycle.

Photo B: After washing, the crops are dried in a covered area on designated racks.

Photo C: The dried material is cut into the required size at the factory.

Photo D: The dried material is then checked for foreign matter.

on medicinal plant collection for their livelihoods.¹⁶ A common pattern can be seen across different countries: As collected plants are depleted in the wild, their scarcity in the marketplace increases along with their economic value. This drives collectors to travel to isolated and potentially dangerous areas in order to find more of the raw material, or to use superficially similar material that can be sourced at lower cost. The collectors themselves, however, are often unaware of the true market value of the plants they collect and are prone to exploitation by middlemen.

Photos ©2016 Anthony Booker

The pressure to find more material may lead to adulteration of the crop with similar species (e.g., as with *Rhodiola* species) or adulteration further down the value chain. Another example is the adulteration of ginkgo products with lower-cost rutin derived from buckwheat (*Fagopyrum esculentum*, Polygonaceae). This is done in order to increase the flavonoid content of the product and to achieve a superficial similarity to some of the existing analytical standards that relate to ginkgo leaf extract. Clearly all such products, if they do not comply with the label claim, are put on the market illegally.

An integrated chain using cultivated material may provide a better alternative to these models, but a major drawback for many manufacturers and retailers is the cost. Cultivated material is typically more expensive than wild-collected material, especially when it is produced in more economically developed countries. This is particularly true for root crops that require a number of years of growth before they can be harvested, such as Asian ginseng (*Panax ginseng*, Araliaceae) and rhodiola. These crops are typically grown for four to six years before harvesting and incur considerable expenditure of both time and money. There are also concerns by some that cultivated material may be in some way inferior to wild-collected material, and that certain cultivated plant-based products may be less appealing to consumers.

Welfare Effects

Some companies, including manufacturers of food supplements containing botanical ingredients, have managed not only to find a way to cultivate their own crops, but also to use the VIVC model to their advantage. In doing so, they highlight to the general public the high quality of their products due to the tight controls employed along the chain, and raise awareness of the potential welfare effects that such chains can have on



the primary producers in less economically developed countries (e.g., in India and Eastern European countries).¹⁷ These welfare effects may not be sizeable in terms of hard cash but can help in some practical ways, and will be of longer-term benefit. For example, farmers can plan their crops based on definite orders, which can give farm workers and those involved in primary processing fixed terms of employment, rather than having to travel the country in search of farm labor or factory-based employment.

The VIVC model has some obvious similarities to the Fairtrade approach.* However, in order to gain Fairtrade certification, farmers need to have a certain amount of infrastructure already in place. Consequently, it is not always a suitable partnership for the poorest farmers.¹⁸ The partnerships that have been built between farmers and companies

Rhodiola crenulata is collected at high altitude on the Chinese Sichuan-Tibet border. *Rhodiola crenulata* is used in the Chinese medicine industry, but based on the *European Pharmacopoeia*, for example, it is an adulterant. In other cases (if no specific label claims are made) it could be considered a substitute. Photo ©2016 Anthony Booker

Table 1. Comparing Benefits and Risks: THR Products vs. Non-THR Products

THR Products	Non-THR Products
Benefits	Risks
Cultivation & Collection Practices	
Quality from the source — Controlled agricultural, cultivation, and collection practices.	Reliance on middlemen — Limited botanical knowledge may lead to misidentification of plant material.
Primary Processing	
According to good manufacturing practices — Batch integrity is maintained throughout processing. In-house quality control.	Variable standards followed — Poor controls, including container, packaging, and storage, can lead to spoilage.
Manufacturing	
Standard operating procedures — Tightly controlled processing leads to consistently high-quality products.	Manufacture may be poorly controlled — Lack of standard procedures can result in lower quality finished products.
Retail	
Defined shelf-life based on extensive stability studies — High confidence in product integrity during specified shelf-life.	Often lacking meaningful stability studies — Prolonged shelf-life can lead to deterioration of product due to spoilage.
Consumers	
Purchases registered product — Consumer has confidence that the product is safe and of good quality.	Purchases unregistered product — Variable quality and safety. Consumers are poorly informed about products.

* Fairtrade (www.fairtrade.net) was established to support farmers and farm workers, mainly in less economically developed countries. The Fairtrade mark gives consumers the knowledge that workers have been paid a fair price and work under a set of agreed-upon working conditions.

producing both regulated and unregulated end products may offer an extra level of support for some of these poorest workers. Of course, a more informal fair-trade VIVC approach can also have its dangers without good governance. Some studies suggest that certain VIVCs, particularly ones that are dominated by a single powerful company, can lead to negative effects on the livelihoods of small producers.¹⁹ Only through the establishment of mutual trust over a period of time (quasi-vertical integration) can these partnerships be successful and flourish.

A comparison of the different value chain approaches along with their main risks and benefits is given in Table 2. In comparing both tables, it becomes apparent that VIVCs and THR-driven supply systems have a number of similarities, most importantly as they relate to the possibility of ascertaining a consistent, high-quality end product.

Conclusion

Overall, to both producers and consumers, VIVCs appear to offer some distinct advantages over the reliance on middlemen that often occurs in a free-market system. However, in a market in which cost may still be the major driving force for most consumers of botanicals and herbal medicinal products, it is unlikely that VIVCs will become commonplace without sufficient consumer-driven demand for a specific group of products (e.g., demand for organically grown raw materials).

The examples presented here offer models for how to ascertain the best quality botanicals and herbal medicinal products. The research highlights not only the need for taking a broader approach with regard to quality control (including an understanding of best practices from source to consumer), but also that either regulation or self-regulation of the relevant industry is essential for quality assurance.

The lack of any government strategies for the effective cultivation, process-management, and regulation of wild-sourced medicinal or locally grown (often by smallholders) plant material — particularly plant material originating from less economically developed countries — is a major cause

for concern for producers, manufacturers, and consumers of plant-based products. However, VIVC-based approaches, which encompass effective partnerships, ethical trading, and good governance, can help provide a more stable platform from which safe and high-quality products can be sustainably produced. HG

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Anthony Booker, PhD, is a senior lecturer in Chinese herbal medicine and medicinal plant science at The University of Westminster in London. In 2014, he received a doctorate from University College London in ethnopharmacy and pharmacognosy. His current post-doctoral projects at UCL investigate medicinal plant value chains and the quality of plant-based products. Email: anthony.booker.11@ucl.ac.uk.

Michael Heinrich, Dr. rer. nat. habil., is a professor at the Centre for Pharmacognosy and Phytotherapy, School of Pharmacy, University of London. Much of his research interest lies in ethnobotany, pharmacognosy, the quality of herbal medicinal products, and designing increased value for herbs along the supply chain. He is the co-author of a textbook on pharmacognosy and a member of the ABC Advisory Board. Email: m.heinrich@ucl.ac.uk.

Table 2. Comparing Benefits and Risks: Vertically Integrated Value Chains vs. Free-Market Approach

Vertically Integrated Value Chains	Free-Market Approach
Benefits	Risks
Cultivation & Collection Practices	
Controlled agricultural, cultivation, and collection practices through on-site training and detailed customer requirements (e.g., organically grown).	Impossible to control or influence collection and cultivation practices. Reliable traceability of defined batches often is lost along the chain.
Primary Processing	
Company is in a stronger position to request and agree to primary processing procedures with the producers.	How the harvested crop is initially processed (e.g., cutting and drying) is largely unknown.
Producers	
Producer benefits from agreeing to known quantities of crops at fixed prices. Staff can benefit from training and input.	Producer may reap greater financial benefits when prices are high but can experience big losses when market prices crash.
Buyers (Retailers)	
Buyer is able to have some control along the length of the chain and plan for following years.	Buyer maintains control of product only after it has been purchased. Buyer can be affected by price fluctuations and shortages.
Consumers	
Good traceability back to the fields or collection areas. May be better quality.	Often little or no traceability. May be lower-cost, but quality may be poorer.

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Key Findings from UCL Investigations of Botanicals and Herbal Medicinal Products

In 2010, the research group of Michael Heinrich, Dr. rer. nat. habil, at the UCL School of Pharmacy in London initiated a series of investigations of the authenticity and identity of various herbal medicinal products and herbal food supplements sold in the United Kingdom and links to different value chains of such products.

In our initial project, we investigated value chains of turmeric, which is grown as a cash crop throughout India.¹² It is generally sold at auction, and the price can be variable from one year to the next. When the price is high one year, it encourages farmers to plant more, frequently resulting in an excess of crop the following year, which usually leads to a fall in the price. This is pure supply-demand economic dynamics. When the price is low, farmers may store the dried crop rather than sell it. The dried turmeric rhizomes can sometimes be stored for years in poor conditions, and farmers can rely on heavy use of pesticides and other chemicals to keep the material from degrading or perishing. Our analytical data suggested that this long-term storage also can result in the loss of therapeutically important, mainly volatile compounds (e.g., tumerone) that can evaporate over time.

We also investigated rhodiola products (i.e., herbal products made from roots of plants in the genus *Rhodiola*). These included both registered herbal products and unregistered food supplements used for the prevention or treatment of fatigue and widely used to improve sports performance. We looked at 39 products available in health food stores and on the internet and found that approximately 25% of these products were of poor quality.¹⁰ The main problem was that an incorrect species had been used. Instead of the preferred *R. rosea* — the species of *Rhodiola* that has the most clinical research — the lower-cost Chinese species *R. crenulata* had been substituted in its place, even though 34 products claimed on the label to contain only *R. rosea*. Although *R. crenulata* is used medicinally in China, it does not contain the important compounds that give *R. rosea* its reputation as an effective adaptogenic medicinal product. More troublesome, a selection of the samples appeared to contain no *Rhodiola* species, and one was found to contain 5-HTP, a naturally occurring compound with reputed antidepressant properties. All of the THR products (n = 10) complied with their label specifications.

With ginkgo and milk thistle, we used a similar sampling strategy to rhodiola, using the internet, visiting high street supermarkets, pharmacies, and health food shops, and obtaining a reasonably representative sample of products available to UK consumers (ginkgo: n = 35; milk thistle: n = 18). Once again we found that 22% of all milk thistle products and 25% of all ginkgo products were of very poor quality when compared to the reference material or to THR products.¹⁴ The quality problems included low concentrations of key compounds (with some being almost undetectable) when compared to reference products commonly used in intervention and clinical studies, and adulteration with other substances. Since the original work was done, we have looked more closely at the ginkgo samples and suggest that more than 50% contain low levels of ginkgo, and thus also are poor quality products. Some ginkgo samples appeared to have greater quantities of rutin than were detectable in the reference material. This suggests that they had been "spiked" — a process in which exogenous rutin is added to increase the total flavonoid content, making it appear that the samples are of acceptable quality. And again we found that one product contained a 5-HTP-related compound. This product was from the same company as the adulterated rhodiola product.