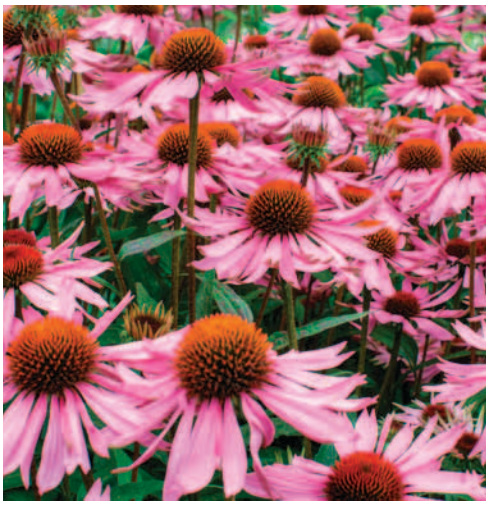

BIOSCIENCE AT A CROSSROADS: BOTANICALS AND THE NAGOYA PROTOCOL*

WHAT ARE BOTANICALS?

Botanicals are plant-based products that are used as medicines or to promote health and well-being. The botanicals sector is diverse, with widely varying products, companies, markets, approaches to research and development (R&D), and regulatory frameworks. Around the world, these products go by a range of names, including herbal medicines, dietary herbal supplements, phytomedicines, phytoprotectants, and phytotherapeutic agents. In contrast to pharmaceuticals, the active constituents in a botanical medicine are often not identified, and its biological activity might not be well characterized. No longer sold primarily as single ingredients, botanicals are now also found as mixtures, in sports drinks, functional foods, cosmetics, and as natural alternatives to artificial colorings, flavorings and preservatives.

GLOBAL MARKETS

Global nutrition industry sales – which include dietary supplements, natural and organic foods, natural personal care, household products, and functional foods – totaled more than $300 billion in 2010. All of these categories might include botanicals to greater or lesser degrees. The botanical medicine portion of the industry was around $84 billion in 2010.

Around the world, there is a growing middle class with more money and more inclination to spend on natural and preventive healthcare. Europe is the world's largest market, led by Germany, France, Italy and the UK. Global demand for botanical and other nutraceutical ingredients is projected to increase 7.2% annually, with emerging economies like China, India and Brazil projected to have the fastest growth in both consumption and production.

* This fact sheet was prepared by Sarah Laird and Rachel Wynberg. For more information, and references, see the full Botanicals policy brief at www.cbd.int/abs.

STRUCTURE OF THE INDUSTRY

Companies vary in size, nature of products, extent of R&D and overall approach. The industry includes small family-run companies that sell a handful of products based on traditional medicine and large pharmaceutical companies that undertake extensive R&D and produce standardized phytomedicines. In most countries, a small group of very large companies dominate the industry, with more numerous smaller companies filling niches.

Raw material typically passes through many hands before landing in a final product, with harvesters and growers, traders, brokers, bulk ingredient and processing companies, manufacturers and marketers, distributors, and retail outlets part of a web of transactions. The existence of this long chain of intermediaries has to be taken into account when implementing the Nagoya Protocol.

DEMAND FOR "NEW" INGREDIENTS AND PRODUCTS

Even though novel ingredients and products are of real interest to the industry, in recent years this interest has slowed down due to regulatory confusion and tightening. In many regions, government oversight of the safety, efficacy, identity, purity and quality of products has increased, requiring more expensive and time-consuming research and testing than previously.

As a result, many companies sell the same portfolio of botanicals they have for decades, and seek growth through expansion into new countries, or new uses of ingredients already on the market.

DEMAND FOR TRADITIONAL KNOWLEDGE

Traditional knowledge is the foundation of the botanicals industry. Unlike most sectors, botanical medicines continue to depend on traditional knowledge. Traditional knowledge is the primary

PHOTOS: Left: Maca, *Lepidium meyenii* / Centre: *Echinacea sp.* / Right: *Prunus africana* (Photo Rachel Wynberg)

guide to new ingredient and product development and is integral to acquiring approval from regulatory agencies, and is used in marketing products to consumers.

Many companies today draw upon European traditional medicine because species have high levels of research to support safety and efficacy. Traditional chinese medicine and Ayurveda are also the source of many new products, supported not only by long histories of traditional use but also increasingly by extensive research.

THE NAGOYA PROTOCOL: RESPONDING TO SCIENTIFIC, TECHNOLOGICAL, POLICY AND MARKET CHANGE

Regulatory frameworks for botanicals are in flux around the world. As governments seek to streamline and harmonize regulations for the safety, quality and efficacy of botanical medicines, they might usefully take note of the obligations set out in the Nagoya Protocol. Implementation of the Nagoya Protocol can therefore help to clarify industry obligations and responsibilities in relation to access and benefit-sharing. In particular, the Nagoya Protocol can assist with the following:

Providing legal certainty and effective and streamlined measures – The Nagoya Protocol seeks to create an environment of legal certainty and mutual trust by requiring Parties to designate a national focal point on ABS to make information available on procedures for obtaining prior informed consent and reaching mutually agreed terms and one or more competent national authorities to grant access (Article 13). Establishment of an ABS Clearing-House (Article 14) for sharing information will also contribute to enhancing transparency and legal certainty. The development of model contractual clauses (Article 19) can reduce transaction costs.

Providing clarity on scope – Many in industry have expressed concern about the inclusion of biological resources within the scope of ABS measures. The scope of the Protocol does not cover the commodity trade of raw materials used in the botanicals sector, local trade, or subsistence use. As clarified by the Protocol (Article 2(c)), ""utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention." Implementation of the Protocol within countries can further help to clarify and resolve the issue of scope.

Supporting the sharing of benefits from the use of traditional knowledge – Traditional knowledge associated with genetic resources is of interest to the botanical medicine sector and is used as a lead for new product development, in seeking regulatory approval, and for marketing. Through Parties' implementation of Articles 7 and 12, the Nagoya Protocol can help Parties, companies and indigenous and local communities to ensure that traditional knowledge associated with genetic resources is accessed and used with the prior informed consent of indigenous and local communities and that mutually agreed terms are established.

Improving monitoring of the use of genetic resources – Botanical products involve multiple ingredients and product lines across several sectors. Through the checkpoints described in Article 17 and the internationally recognized certificate of compliance, the Nagoya Protocol can help to monitor the use of genetic resources throughout the botanicals supply chains and provide evidence that prior informed consent has been obtained, that mutually agreed terms have been established.

Building the capacity of governments, researchers and companies to engage with ABS and changing scientific and technological developments – Awareness of the CBD and the Nagoya Protocol within the botanicals sector is limited, and appears to have not increased in the last few decades. Companies and academic researchers can benefit from capacity built within country governments under the Protocol. Articles 21 and 22 of the Protocol call for strengthening human resources and institutional capacities, and raising awareness of ABS issues.

Developing regional ABS approaches – Many species and traditional knowledge associated with botanicals are widely distributed across political boundaries. Implementation of Article 11 on transboundary cooperation provides important opportunities to investigate common regional or sub-regional ABS approaches for such resources and knowledge. Consideration of the need for and modalities of a global multilateral benefit-sharing mechanism, as required by Article 10 of the Protocol, may also be of relevance in this context. These efforts should seek to dovetail where possible with existing regional efforts to harmonize regulations of safety, efficacy, and quality-control within the botanicals industry.

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