Access and Benefit Sharing

Key Points for Policy-Makers

THE BOTANICALS INDUSTRY

THE ABS CAPACITY DEVELOPMENT INITIATIVE

People and Plants international

University of Cape Town • iYunivesithi yaseKapa • Universiteit van Kaapstad

SPES BONA

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SUMMARY OF KEY POINTS

WHAT ARE BOTANICALS?

- Botanicals are plant-based products that are used as medicines or to promote health and well-being. All parts of plants are used including roots, bark, leaves, seeds and flowers.
- Other names for these products include herbal medicines, dietary herbal supplements, phytomedicines, and phyotherapeutic agents.
- Unlike pharmaceuticals, botanicals are not highly purified or chemically modified medicines and typically do not involve identification of active constituents and characterisation of biological activity.

MARKET TRENDS

- Botanical medicine sectors vary by country, reflecting the medical, scientific, cultural, legal and economic context from which they emerge. This sector varies more than most – including size of companies and sales, products, extent of R&D, and regulatory frameworks.
- To different degrees, botanicals are part of the larger global nutrition industry – which includes dietary supplements, natural and organic foods, natural personal care, household products, and functional foods.
- There is a global trend towards acquisitions of smaller botanicals companies by large pharmaceutical, personal care, household product, and food companies. Remaining small companies in the sector tend to fill niches, which might include sustainable and fair trade products.

PRODUCTS

- Increased consumer demand for quality products with proven safety, efficacy, purity and consistency has led manufacturing companies to seek branded ingredients with better documentation, and clinically proven health benefits.
- Regional variations exist in products sold, but global trends influencing new product development include: demand for high value products to treat the problems of affluent, aging and high stress populations, as well as performance-enhancing products for sports and active lifestyles.
- Spices and food-based products are increasingly sold as botanical products for their medicinal and wellness-enhancing qualities (e.g. cranberry, garlic, turmeric, oregano, cinnamon and ginger).
- Some botanical medicines are single species, and others are species combinations. They are sold in many forms, including: tablets, capsules, powder, liquid extracts, softgels, gelcaps, or as ingredients in sports drinks, energy bars and other functional foods.

DEMAND FOR ACCESS TO RESOURCES

- There is increased interest in novel ingredients and innovation continues to be important, but new species are largely introduced to the market by smaller companies.
- Investments in research on safety, efficiency, quality, formulations and delivery systems and in packaging and marketing, will often provide greater returns than gaining access to novel ingredients through ABS agreements.
- Greater government oversight of safety, efficacy, and quality means the introduction of new species is more expensive and time-consuming than previously. Long histories of traditional use are sometimes used as proof of the safety and efficacy of botanical products.
- Patents are an increasing part of R&D and product development strategies.

DEMAND FOR TRADITIONAL KNOWLEDGE

- Traditional knowledge remains important to companies for identifying new products, marketing, and acquiring regulatory approval.
- Increased consumer interest in natural products and stories associated with indigenous communities has increased the use of traditional knowledge in marketing and branding.

ETHICAL AND SUSTAINABLE SOURCING

- Raw material typically passes through many hands before landing in a final product. This makes tracking of material for regulatory purposes, including ABS, very difficult.
- There is growing consumer interest in green and fair trade certification for raw materials.
- The sector is characterised by booms and busts in demand for products.
- Agreements between companies and communities for biotrade, or raw material sourcing, are more common than ABS agreements focused on research and development of new ingredients and products.

INDUSTRY AND ABS

- Companies tend to have very low levels of awareness of the CBD and Nagoya Protocol, although this varies by region. In some regions, compliance with the CBD and national ABS measures is viewed increasingly as a business opportunity.

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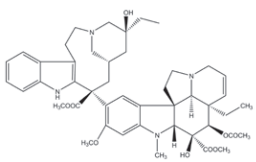
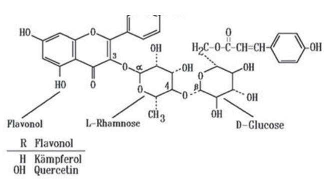
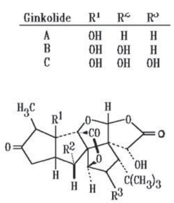


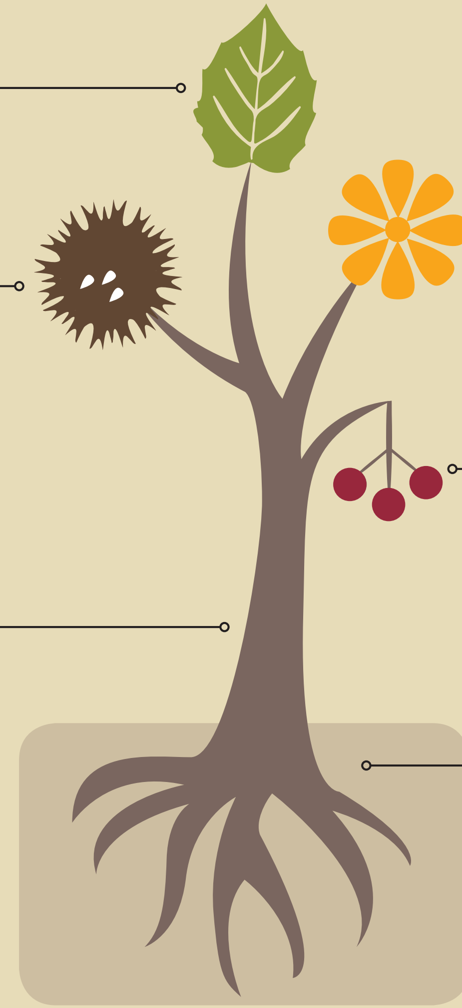
The isolated pharmaceutical compound Vincristine, derived from *Catharanthus roseus*

A few of the compounds found in *Gingko biloba* botanical medicines





Plants parts used in selected top-selling botanicals



LEAVES
Senna
(Senna alexandura)
Gingko
(Gingko biloba)

SEEDS
Milk Thistle
(Silybum marianum)
Flax seed
(Linum usitatissimum)

BARK
Yohimbe
(Pausinystalia yohimbe)
Pau d'Arco
(Tabebuia spp.)

FLOWER
St. John's Wort
(Hypericum perforatum)

FRUIT
Elderberry
(Sambucus nigra)
Cranberry
(Vaccinium macrocarpon)
Saw Palmetto
(Serenoa repens)

ROOT
Kava
(Piper methysticum)
Maca
(Lepidium meyenii)
Ginseng
(Panax spp.)
Black Cohosh
(Actaea racemosa)

MARKET TRENDS

Botanical medicine sectors vary by country, reflecting the medical, scientific, cultural, legal and economic context from which they emerge. This sector varies more than most – including size of companies and sales, products, extent of R&D, and regulatory frameworks.

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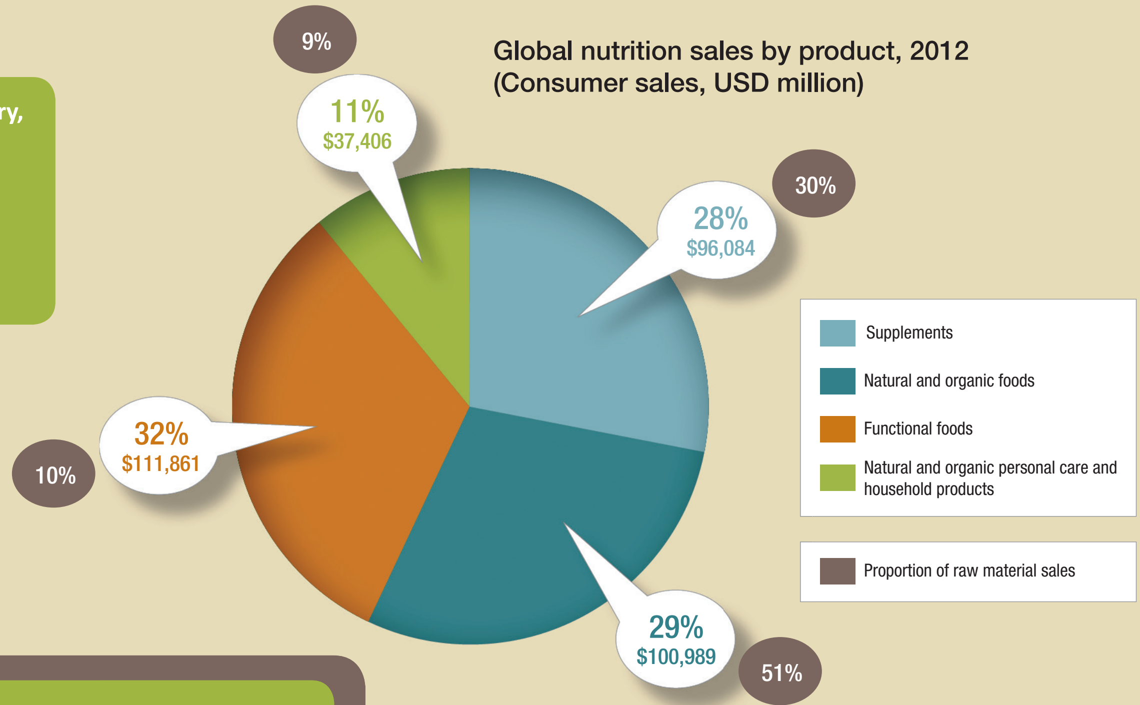
Global nutrition sales by product, 2012
(Consumer sales, USD million)



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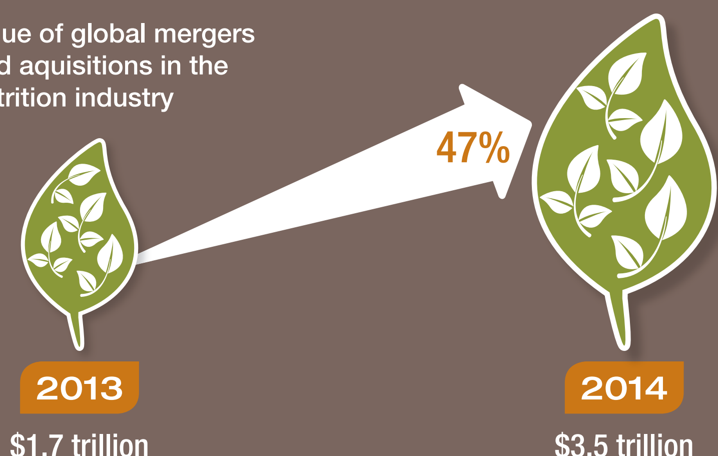
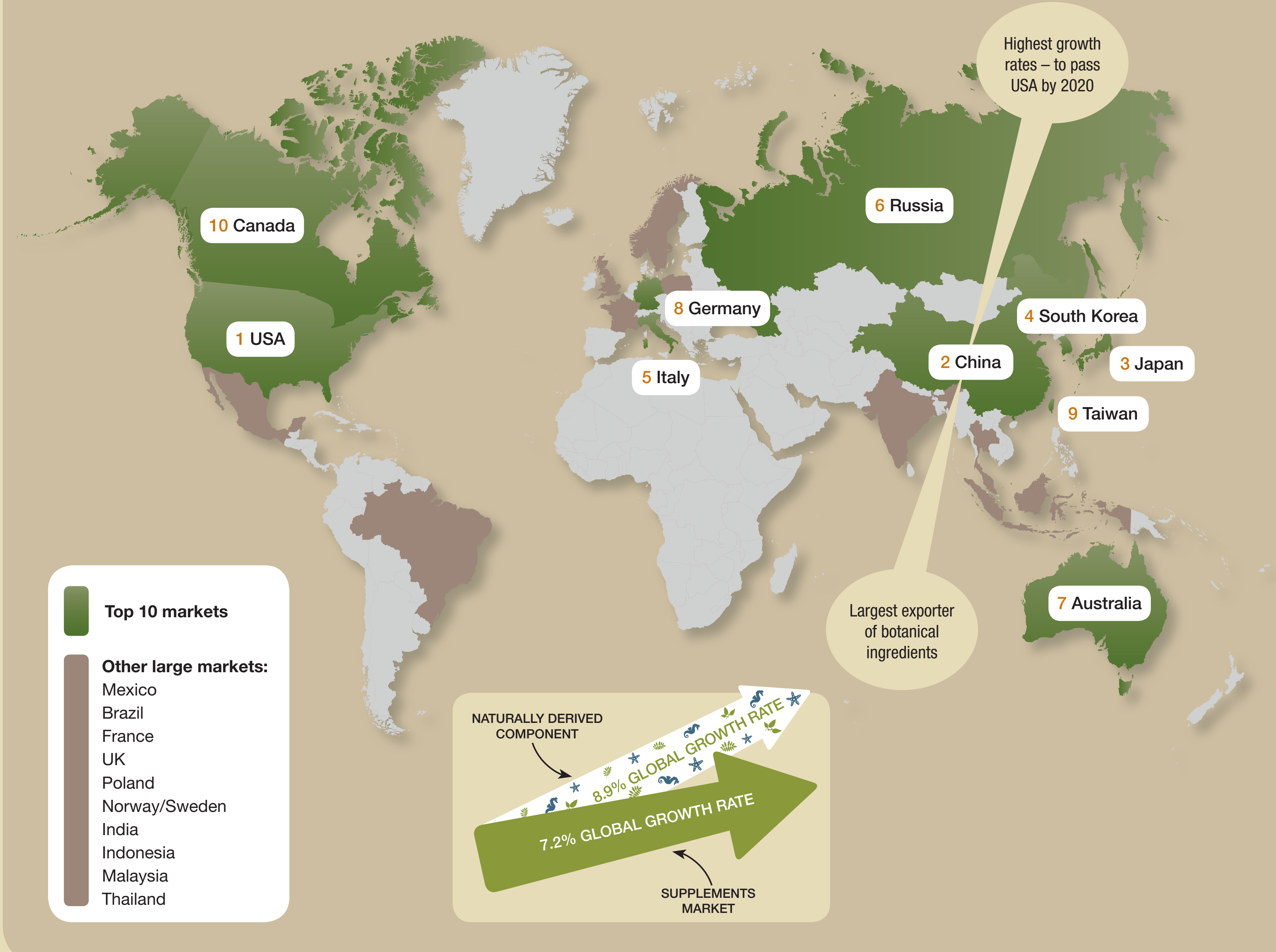
Value of global mergers and aquisitions in the nutrition industry



Growth in global supplements market (USD billion)
(botanical medicines, vitamins and minerals)

Global supplements markets



Trends impacting botanical medicine use and development

Increased consumer demand for quality products with proven safety, efficacy, purity and consistency has led manufacturing companies to seek branded ingredients with better documentation, and clinically proven health benefits.

Regional variations exist in products sold, but global trends influencing new product development include: demand for high value products to treat the problems of affluent, aging and high stress populations, as well as performance-enhancing products for sports and active lifestyles.

Spices and food-based products are increasingly sold as botanical products for their medicinal and wellness-enhancing qualities (e.g. cranberry, garlic, turmeric, oregano, cinnamon and ginger).

The 20 top-selling herbal dietary supplements in the USA, 2013

	Herb	Latin Name	Geographic Origins	Sales (USD million)
1	Horehound	*Marrubium vulgare*	Europe, North Africa, SW Central Asia	$106,897,772
2	Yohimbe	*Pausinystalia yohimbe*	Central Africa	$ 67,393,961
3	Cranberry	*Vaccinium macrocarpon*	North America	$ 48,808,893
4	Black Cohosh	*Actaea racemosa*	North America	$ 45,967,801
5	Senna	*Senna alexandrina*	North Africa	$ 32,260,528
6	Cinnamon	*Cinnamon spp.*	Asia	$ 29,525,719
7	Flaxseed	*Linum usitatissimum*	Europe, Mediterranean	$ 28,363,954
8	Echinacea	*Echinacea spp.*	North America	$ 28,277,149
9	Valerian	*Valeriana officinalis*	Eurasia	$ 28,258,909
10	Saw Palmetto	*Serenoa repens*	North American	$ 21,612,897
11	Aloe Vera	*Aloe vera*	South Africa	$ 18,243,186
12	Bioflavenoid complex	*Citrus spp.*	South and Southeast Asia	$ 16,332,400
13	Milk Thistle	*Silybum marianum*	North America	$ 16,293,694
14	Ginger	*Zingiber officinale*	Asia	$ 16,203,615
15	Horny Goat Weed	*Epimedium spp.*	North Africa/Asia	$ 15,086,408
16	Garlic	*Allium sativum*	Eurasia	$ 14,520,837
17	Red Yeast Rice	*Monascus purpureus*	Asia	$ 11,952,456
18	Gingko	*Gingko biloba*	Asia	$ 11,603,100
19	Horsetail	*Equisetum spp.*	Cosmopolitain, Europe	$ 11,159,101
20	Bromelain	*Ananas comosus*	South America	$ 8,755,864

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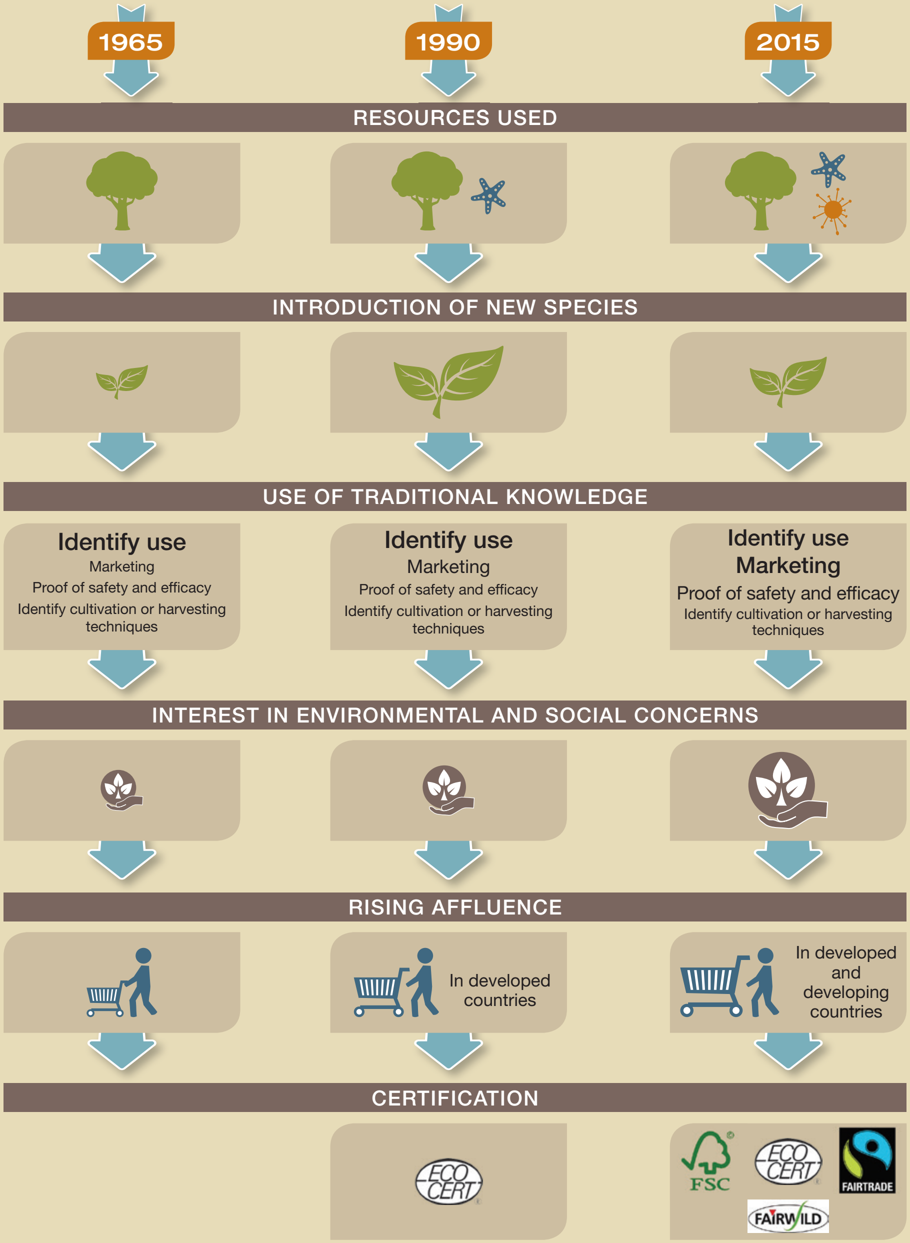
DEMAND FOR ACCESS TO RESOURCES

TRENDS IN DEMAND FOR ACCESS AND PRODUCTS



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Patents are an increasing part of R&D and product development strategies.

	SPECIES	PUBLICATIONS[1]	CLAIMS[2]
1	*Aloe vera*	3416	4257
2	*Gingko biloba*	1297	2964
3	*Silybum marianum*	275	824
4	*Serenoa repens*	295	696
5	*Centella asiatica*	485	693
6	*Hypericum perforatum*	440	648
7	*Echinacea purpurea* and *E. augustifolium*	268	787
8	*Curcuma longa*	548	534
9	*Panax ginseng* and *P. quinquefolius*	847	683
10	*Uncaria tomentosa*	133	470
11	*Hoodia gordonii*	68	379
12	*Arnica montana*	233	330
13	*Astragalus propinquus*	137	269
14	*Vaccinium myrtillus*	232	247
15	*Prunus africana*	114	229

1 'Publication' refers to publication of patent applications, not an issued patent;
2 'Claim' refers to the scope of the protection covered by a patent, or the protection sought in a patent application.

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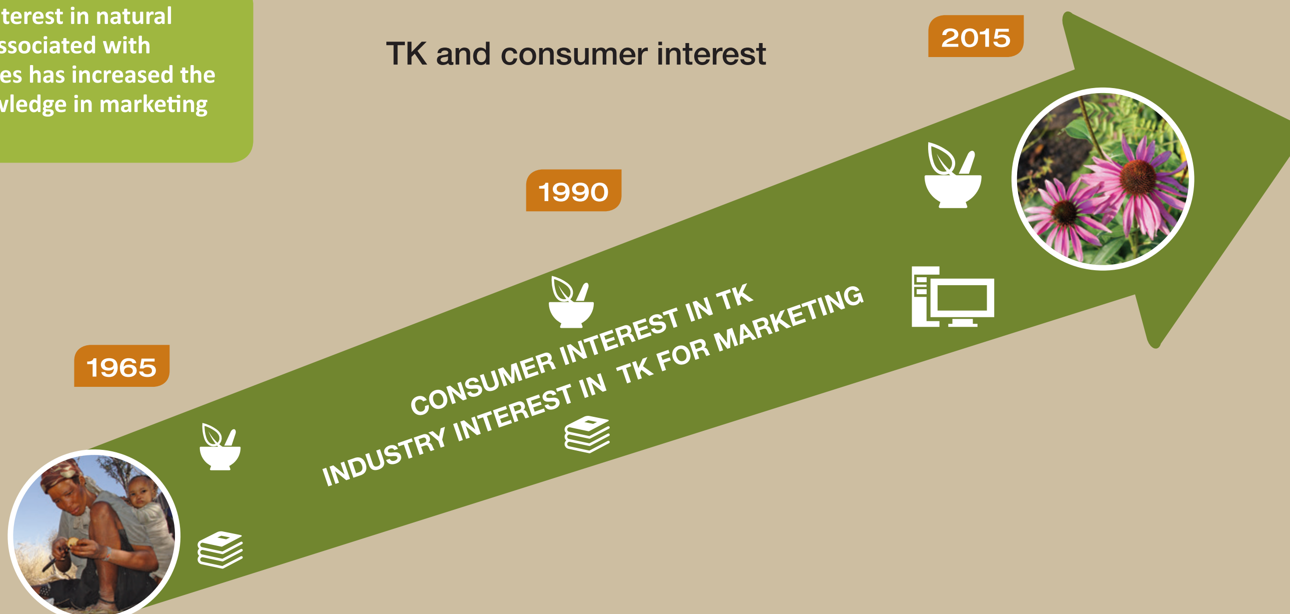
TK and consumer interest



Sources of TK

- Ethnobotanical collections
- Internet / databases
- Literature

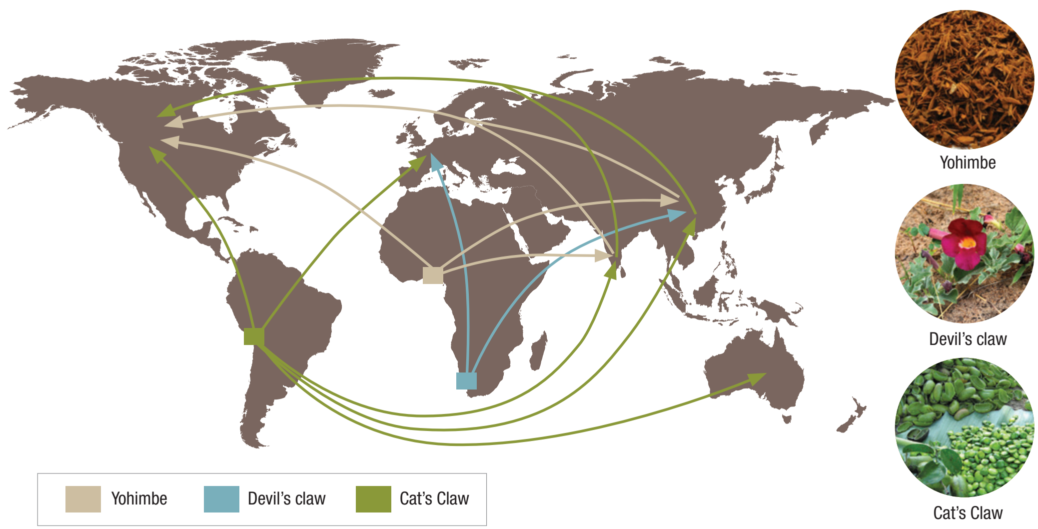
ETHICAL AND SUSTAINABLE SOURCING

Raw material typically passes through many hands before landing in a final product. This makes tracking of material for regulatory purposes, including ABS, very difficult.

The travels of a botanical

- Harvester or Farmer
- Trader ······> Leaves the region of collection
- Broker ······> Often leaves the country of origin
- Bulk ingredient processor ······> Often found in low-cost labour centres on different continents ······> R&D for high value products
- Manufacturing and Marketing companies
- Distributors
- Retail outlet/ Internet
- Consumer

The many miles travelled by a botanical ingredient:
the case of three species



The sector is characterised by booms and busts in demand for products.

There is growing consumer interest in green and fair trade certification for raw materials.

Agreements between companies and communities for biotrade, or raw material sourcing, are more common than ABS agreements focused on research and development of new ingredients and products.

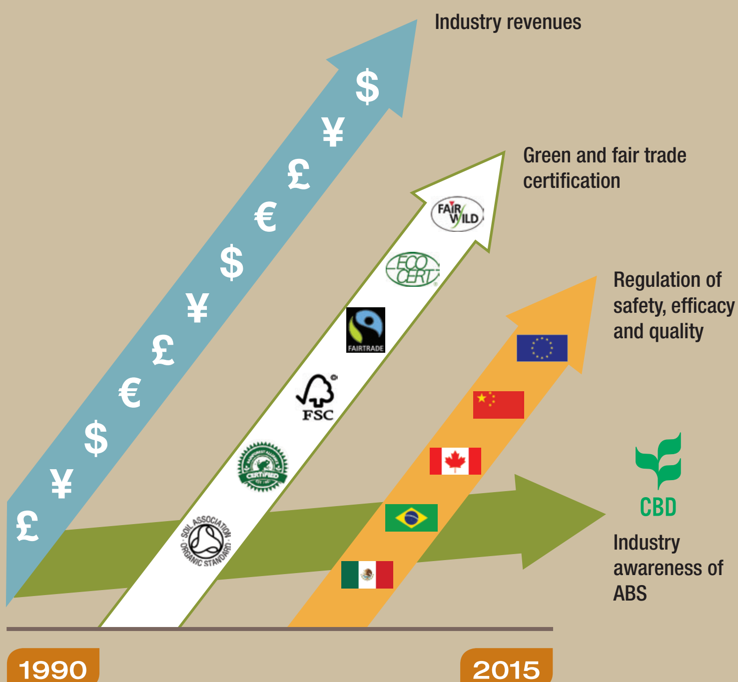
> *There has been a trend towards cleaner and greener products. Consumers today want to know more – what it is, where it came from, how it was produced. Sustainability and fair trade labels are growing, and maybe later in the process will come ABS and ethics, but those are still not something consumers, or most companies, think about.*
>
> – Industry representative in the US

INDUSTRY AND ABS

Companies tend to have very low levels of awareness of the CBD and Nagoya Protocol, although this varies by region. In some regions, compliance with the CBD and national ABS measures is viewed increasingly as a business opportunity.

> *Some companies are beginning to ask about regulations, including the CBD, and want to be in compliance with ABS. It is starting to be a market advantage against our competitors that we can bring clarity and certainty to the customer that the supply chain is ABS compliant.*
>
> – Manager, ingredient supply company

The botanical sector (1990 – 2015)



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www.abs-initiative.info

www.bio-economy.org.za

www.peopleandplants.org

The Access and Benefit-Sharing Key Points for Policy-Makers series has been produced to provide governments, companies, researchers, communities and others with background information to assist with the development of access and benefit-sharing measures to implement the Nagoya Protocol. The briefs are organised around central, key points on trends and practices in markets, research and development, and ABS. More detailed information on these sectors can be found at: www.bio-economy.org.za; www.abs-initiative.info; www.peopleandplants.org; CBD Bioscience at a Crossroads policy briefs: https://www.cbd.int/abs/policy-brief/default.shtml/; and in the upcoming book: http://www.routledge.com/books/details/9781138779099/

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