

Herbal products market research



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Abstract:

Herbal products have gained a lot of attention in the recent years. This has pushed natural and nutraceuticals companies globally to take interest in these products. Herbal extracts are no longer a concoction of plants but are sophisticated standardized extracts. This has led countries all over the world to set regulatory guidelines and policies in order to maintain good quality, standardized herbal medicines. Konark Herbals & Health Care, an India based company, manufactures solid and liquid herbal extracts in semi finished form. The company recently has decided to launch its products globally. This project focuses on opportunities of herbal products in the European Market i. e. the European Union. Europe being the central hub of herbal medicines is integrated with a number of regulatory guidelines set by the EU. The project aims at understanding these regulatory policies, gauging the market scenario and presenting ideas for launching the company's products by creating its place in the market. The main objective of this project was to gain an understanding of the herbal products already in the market and finding newer opportunity for its use

Introduction**About the Company**

Konark Herbals and Healthcare is a medium sized company established in 2004. The company is into manufacturing and selling of semi finished herbal products. These products include soft and dry herbal extracts, in both solid and liquid form. The company is also associated with the Konark Research foundation which carries out all the quality assurance and testing to ensure

quality and standardised products. Konark manufactures over 300 herbals extracts, though its flagship product is curcumin and its derivatives.

Up until 2010 the company's main focus was the domestic market. The products were marketed and sold either for domestic use or to other Indian companies for export purposes. The main problem faced by Konark was the competitive prices. The company also found that since the regulations in India were not very strict most competitive suppliers would sell sub standard quality products at a cheaper rate. A thorough study was done to understand the pros and cons of focusing on the domestic market. Therefore Konark Herbals and Health Care decided to launch its products globally. Therefore, this report focuses on opportunities of herbal products in the European market.

Traditional Medicine has always had its popularity worldwide. In addition over the last few years there has been increase in the use of complementary and alternative medicines (CAMs) in many developed and developing countries. The last 15 years have seen an increase in the popularity of plant based medicines in the western world. Therefore the safety and quality of the CAMs have become very important concerns for the health authorities as well as the public. Several traditional medicine practices have been developed over the centuries in different cultures – but without a parallel advance of international standards and using inappropriate methods for evaluating traditional medicine. Therefore strict guidelines and policies for herbal medicines are critical to the continued existence of quality products.

Even though India and China are known for their herbal medicines since centuries, the hub of herbal products is Europe. More than 60% of the Europeans and greater than 80% of Germans (Figure 1) have used herbal products at some point of time in their life. Herbal remedies which we earlier sold in small special shops, often without any license, have now become mainstream drugs manufactured by multinational companies and sold in pharmacies throughout Europe. It is due to this high usage of products that the European Union has an extensive set of guidelines for herbal products. The EU has laid down guidelines and policies for all the processes related to these herbal products from manufacturing right up to market authorization and which it expects all to adhere to.

European Union

Overall Market Size

The member states of the European Union represent the largest single commercial market for herbal drugs and medicinal plants in the world. The European market for herbal supplements along with herbal medicines is currently at \$7.4 billion. An analysis based on the data from IMS health placed the global European over the counter (OTC) market for herbal medicines at approximately \$5 billion.

Imports

The EU is also the largest importer of Crude medicinal plants and herbal extracts with imports approximated at around 100,000 tonne. This is almost double the quantity imported by the USA (IMS report). Germany is the most important European importer with 40% of the European market followed by France and Italy.

European Guidelines

Europe consists of 50 countries. And each country has its own regulatory guidelines and policies. It is important to know that out of the 50 countries only 27 countries fall under the European Union. Legislation in the European Union is set at the EU level, but there may be (additional) legal requirements which may be country specific. Although maximum synchronization is aimed it is not always achieved because of negotiations, debates and national interest. The European Medical agency along with the THMPD (Therapeutic herbal Medical product directive) are the two many regulatory bodies within the European Union. Each of the two bodies has a set of guidelines which has to be followed by not only the companies within Europe but also the companies that want to enter the European market for business opportunities. It includes policies from cultivation right up to marketing of the product in Europe. Understanding these guidelines is necessary for Indian companies such as Konark Herbs & Health Care because in order to enter the European markets, they need to abide by them.

The committee on Herbal Medicinal products (HMPC)

HMPC, a part of the European Medical Agency, is responsible for preparing the agency's opinions on herbal medicines. In 2004 it replaced the proprietary medicinal products working party on herbal products which introduced a simplified registration procedure for herbal drugs in EU member states. The committee has the responsibility to prepare monographs of well established herbal medicines which is based on evaluation of available scientific data or on its traditional use in the European community. The monograph includes uses, safety information and information on undesirable effects.

Traditional Herbal Medicinal Product Directive (formerly The Directive 2004/24/EC)

The THMPD was established in 2004 to provide a simplified regulatory approval process for traditional herbal medicines in the EU. Under this regulation all herbal medicinal products are required to obtain an authorization to market within the EU. As per the THMPD all products marketed before this legislation came into force can market their product till 30 April, 2011. Once this limit expires they must gain market authorization.

These guidelines are of great importance especially during the audits done by the European companies. As a mandatory procedure, all European companies conduct a thorough audit of the manufacturing facilities of the suppliers to check them for GMP compliance. The audit even checks for Good Agricultural practices (GAP) complied by the farmers supplying the crude plants to the supplier. GAP includes various documents and certificates that the supplier must have from the farmers. In case any of the guidelines are not met with, the supplier is not only rejected but is blacklisted by the company for future purposes until such time that the supplier has proven to be GMP and GAP compliant. Therefore the suppliers cannot afford to make any mistakes

Examples of EU legislations relevant for herbal products:

Directive 2001/83/EC on marketing authorization for medicinal products for human use, including homeopathic products and herbal medicines.

Directive 2003/94/EC on the principles and guidelines of GMP for medicinal products for human use

Phytosanitary measures. – Directive 2000/29/EC

Regulation 338/97 on the protection of endangered species in trade, CITES

Preventive measures on organisms harmful to plants – Directive 2000/29/EC

Country Profiles

Out of the 27 countries belonging to the European Union few countries such as Germany, UK and France are the major markets for herbal products. As mentioned earlier EU legislations are set at the EU level, but there may be country specific (additional) legal requirements. Understanding the guidelines for each of the countries is crucial because it is through these countries that Indian companies will make their entrance into the European Herbal Markets.

Germany:

Germany by far is the most important consumer of plant based medicines in Europe which accounts for more than 50 % of all European licensed herbal product sales. It is also the largest producers of herbal phytomedicines. Cultivation in Germany has declined massively over the years, which has lead companies to import herbal extracts from other countries such as India and China. This proves advantageous for Indian companies. It is also important to notice that even though Germany does have domestic cultivation, only 5% – 10 % of the total requirement is covered by the domestic production. Germany is by far the largest importer of medicinal plants and extracts with imports of around 50, 000 tonnes on a yearly basis. The basis of market authorization in Germany has been laid out in the Second Medicines Act which was formed in accordance with the EU

legislative framework. It required a review of the safety and quality of 300 plants. This was done by a team of experts known as the Commission E who published more than 235 medicinal plants.

Germany is one of the very few countries that consider herbal products as medicines thereby providing complete reimbursement of such products. The herbal drugs are reimbursable by the health insurance system unless special criteria for their exclusions apply. These exclusions are due to negative assessment by commission E. There are 380 monographs presented in the American Botanical Council's "The Complete German Commission E Monographs, Therapeutic Guide to Herbal Medicines", which has recently been translated into English. The monographs include lists of approved and unapproved herbs, uses, indications, side effects, interactions of herbs with conventional drugs and duration of administration.

German Regulations:

A national pharmacopoeia, the Deutsches Arzneibuch and the European Pharmacopoeia are used, both of which are considered to be legally binding. A number of additional monographs have also been issued such as the Deutscher Arzneimittel Codex but are not legally binding. Regulatory Requirement for the manufacture of herbal medicines include adherence to the information in the pharmacopoeias. In the absence of pharmacopoeias, monographs, the GMP rules for conventional pharmaceutical, German Medicines Act and the Eudralex. Compliance with these requirements is ensured through inspection. Herbal medicines are sold in Germany in pharmacies as OTC and prescription medicines in special outlets and supermarkets.

Advantages for an Indian Company to supply to German companies:

- Not more than 10% of the total requirement is covered by domestic market
- Only a handful of herbal plants are cultivated in Germany as compared to India.
- As per the adapted from BAH (Figure 2) more than a 100 Indian medicinal plants can cater to these therapeutic categories.
- Many Indian plants such as curcumin, Amla, Ashwagandha or on the positive list of commission E.
- Several curcumin products are reimbursed by the health insurance system.

France:

France is both a major producer and consumer of medicinal plants. It is the second largest market in Europe after Germany. It has more than 4000 hectares under cultivation of which over 30% is dedicated to plants such as thyme fennel chamomile and peppermint. Southern France is a major market for essential oils and aromatherapy. France imports around 30, 000 tonnes of medicinal plants and extracts from countries such as India and China. France is also an exporter of medicinal plants which is about 8000 tonnes on a yearly basis. Most exports are simply intra – European consignments often within same company.

French regulations make it difficult to sell unlicensed herbal remedies.

Around 527 medicinal plants are listed in the French Pharmacopoeia of which 454 plants are contained in list A (positive benefit /risk ratio). These include

plants such as acacia. Curcumin, Aloe Vera etc. Plants such as tobacco and Thuja fall under list B that has a negative benefit/risk ratio.

Despite all this, herbal medicines are classified as medicines in France and are subject to market authorization under the Health ministry.

Guidelines:

The French Republic does not have any national policy, laws, expert committee or national research institute on traditional medicines. Herbal medicines are regulated as OTC medicines and by law claims may be made about them. The same GMP rules for manufacture are applicable for herbal medicines as for the conventional medicines. Compliance with the requirements is ensured through inspections. Safety requirements are the same as that for conventional drugs. Out of 787 medicines registered none, are listed on national essential drug list.

Advantages for Indian companies to target France:

- France is the Hub for essential oils and aromatherapy products. Therefore many Indian companies can supply oils such as cinnamon oil, turmeric oil etc.
- Out of the plants listed in List A of the French Pharmacopoeia more than 250 plants are available in abundance in India.
- Although the government is coming up with newer policies, cultivation in France is only for a minor group of medicinal plants. Therefore French companies have to look at supplier of plants and extracts.

United Kingdom

United Kingdom (U. K.) has until recently been well below that of many European countries. U. K. based MNCs have given limited importance to research in herbal drugs. British farmers too have not given much importance to medicinal plants. Less than 2000 hectares are devoted to medicinal plants. But consumption of herbal medicines has been growing at the rate of 10% (WHO report, 2008)

Although U. K. has no single national office, the medicines and Healthcare product regulatory agency and the department of health in England have numerous teams to develop policy on the safe use and practice of traditional medicines. Herbal medicines are regulated under Medicines Act 1968 (2001/83, EC also applies). Until 2011 the directive provided two regulatory routes for herbal medicines to reach the market i. e licensed herbal medicines and unlicensed herbal medicines. Since May 2011 unlicensed herbal medicines have been ban in the market.

The British Pharmacopoeia contains 124 national monographs. There are around 500 licensed herbal drugs in the U. K. but none are included in the national essential list. Herbal drugs are sold in pharmacies as OTC and prescription medicines.

Overview of the top diseases affecting European human population

Chronic diseases are the main cause of mortality in Europe. Research (by EDEC) suggests that complex conditions such as diabetes, depression and dementia will impose a prominent burden in the future. Some years ago chronic diseases were considered to be a problem of only the rich and

elderly people. But today we know that which high income countries, poor as well as young people are affected by these chronic diseases. The implications of the diseases are also very serious.

There are a number of chronic diseases that affect people all over Europe.

The most prevalent ones are:

- Depression
- Obesity
- Diabetes Mellitus
- Alzheimer's disease
- Parkinson's disease
- Dementia
- Schizophrenia
- COPD

The link between disease and age is crucial from an economic public policy standpoint. The proportion of Europeans aged 65 years and older is projected to grow from 15% to 23% by 2030. This trend is clearly one of the many reasons for the growing burden of chronic diseases in Europe.

(Pomerleau, Knai and Nolte, 2008).

The prevalence of mental disorders is very high in Europe. Dementia amongst those who are aged i. e. 65 and above, in 2000 was estimated to vary between 6% to about 8 %. WHO has estimated that one in five persons will develop depression and each year 33 million European suffer from major depression. In 2008, the rates were lowest in Spain, Greece and Portugal while the highest estimates were for Finland, Israel, Belgium and France.

Suicide from depressive disorders is the third leading cause of death among young Europeans.

Top diseases affecting livestock in Europe

Novel strategies and responses are necessary to meet the economic and human health risks that are associated with livestock diseases. Human-health threats from livestock come in two basic forms: (i) zoonotic diseases, and (ii) food-borne illnesses. Zoonotic diseases are those diseases that arise in animals but can also be transmitted to humans. Potentially pandemic viruses, such as influenza, are the most newsworthy, but many others, including rabies, brucellosis and anthrax also do exist. Food-borne illness can come from disease agents such as salmonella and E. coli.

Highly pathogenic livestock diseases remain alarming for the people of Europe because:

- They are still highly pathogenic for humans.
- They are continuing to evolve.
- There is a risk of generic recombination with the viruses that are better adapted to, and can be easily transmitted among humans.

The diseases affecting livestock in Europe include:

- Livestock Disease
- Avian influenza
- Bovine Tuberculosis
- Rabies
- Bovine Brucellosis
- Transmissible spongiform encephalopathies (TSE)

- Ovine and Caprine brucellosis (B. Melitensis)
- Salmonellosis (zoonotic salmonella)
- Livestock Disease
- Avian influenza
- Ovine and Caprine brucellosis (B. Melitensis)
- Salmonellosis (zoonotic salmonella)
- African Swine Fever
- Bluetongue (High risk endemic areas)

Methodology

The main product to be launched by the company being Curcumin and its various derivatives, a secondary research was conducted to gain an understanding about the product. Such a research gave an idea about its current use globally. Various companies across the globe are already manufacturing curcumin products and supplements therefore the product per se is not a novel product. But by understanding its current use it is possible to point out the areas that have never been explored. Companies such as Indena, Sabinsa, and Sigma Aldrich have been selling curcumin supplements over a decade. But it is astonishing to see that even today the full potential of curcumin and its derivatives has not been realized. This gives a possibility for companies to use such products for newer diseases. Reviewing diseases affecting Europe serves great importance since it explains the need for drugs in those sectors and consequentially the unmet medical need.

About Curcumin

Curcumin is a hydrophobic polyphenol derived from the rhizome *Curcuma longa* (Turmeric). It is a gold-coloured spice frequently used in India, not just for health care but also for the preservation of food and as a dye for textiles. Since the time of Ayurveda (1900BC) numerous therapeutic actions have been assigned to curcumin for a selection of diseases, including skin diseases, pulmonary, and gastrointestinal systems, wounds, sprains, allergies and liver disorders. It is in the last few decades that curcumin has gained a lot of attention by researchers, scientists and nutraceuticals companies worldwide. It is due to this, that there have been more than a hundred experiments been conducted in animals and plants for various diseases.

Konark Herbals and Health Care has a vast portfolio of curcumin extracts of various standards. The company manufactures the extract from 1% curcuminoid content up to 99% curcuminoids.

KHHC products

Curcuma longa powder extract (Total curcuminoids NLT 95% by HPLC/UV spectrophotometer)

Curcuma longa powder extract (Total curcuminoids NLT 40% by HPLC/UV spectrophotometer)

Curcuma longa powder extract (Total curcuminoids NLT 10% by HPLC/UV spectrophotometer)

Curcuma longa Granular (Total curcuminoids NLT 95% by HPLC/UV spectrophotometer)

Curcuma longa Granular (Total curcuminoids NLT 85% by HPLC/UV spectrophotometer)

Uses

There have been various trials conducted for a wide variety of diseases most of which have been successful but have not received their due. Below is a short summary of the various uses of curcumin

Neurological Disorders: Curcumin being a potent anti inflammatory agent has found its use in a number of diseases. Various trials have been conducted for its use against several neurological disorders. Current treatments for the majority of these diseases have not succeeded adequate until now. Both of oxidative damage and inflammation have been proved as having roles in age-related neurodegenerative diseases. Because of its pluripotency, oral safety, prolonged history of use, and low cost, curcumin has huge potential for the prevention of numerous neurological conditions for which present therapeutics are less than optimal.

- Parkinson's disease
- Alzheimer's disease
- Schizophrenia
- Depression

Oncology: It has been proved that curcumin is an anti oxidant. This property of the molecule has allowed it use for several diseases such as diabetes

mellitus, obesity, and metabolic syndrome. The anti oxidant property has potentiated its use even in the field of oncology which today is by far the most researched therapeutic category. Studies done on animals and humans have proved promising in more than just one type of cancer. There have been a number of articles published in journals all over the world regarding its potential use against prostate cancer, pancreatic cancer breast cancer and even blood cancer.

Antibacterial Activity: Yet another property of curcumin is its proven use in the antibacterial and antifungal category. Curcumin was known to have antibacterial property since centuries but only recent experiments and research have proved its antibacterial activity. This has not only interested physicians but also veterinarians in potentially using curcumin as a topical drug.

Patents

The according to the Intellectual property rights, the use of curcumin cannot be patented since it is protected by traditional Knowledge of the country. But there have been several patents granted for novel drug delivery system of curcumin. The reason for modifying the molecule developing new delivery systems is because curcumin is a hydrophobic molecule and hence it has a low bioavailability. In order to over this problem researchers have formulated various novel systems to enhance its bioavailability. Understanding the current patents held for curcumin is needed because it shows how advance the industry is. A list of a few patents has been given below

- Water soluble curcumin based compounds , US patent application

- Curcumin Dextrin combinations, US patent application
- Buccal Drug Delivery System for Curcumin, US patent application
- Vaginal drug Delivery of curcumin, US patent application
- Spray freeze dry for pulmonary administration, US patent application

Potential launch of curcumin products for Diabetes Mellitus – Type 2:

Diabetes is a chronic disease that arises when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. This leads to raised glucose levels in the blood and can cause long-term damage to the body and failure of various organs and tissues. Currently about 55 million Europeans are affected by diabetes Mellitus type 2.

Studies conducted at research institutes have proven the effect of curcumin against diabetes. A comprehensive study was done on the diseases and the use of curcumin against various symptoms of the disease. A matrix approach was taken up. (As suggested by Dr Arun Bhatt, Clininvent) With the help of secondary research it was observed that curcumin can treat almost all symptoms relating to diabetes. Various poly herbal formulations are also in the development stage at Konark herbals and health care which have the potential to treat diabetic conditions. Through the research it was observed that several herbs in combination with curcumin could be used against the diabetic symptoms. Curcumin also has shown positive results for reducing cholesterol and LDL levels in the body i. e. preventing obesity. This can give curcumin an opportunity to act as a drug for pre diabetic syndrome. This can

have a much better market since it has been observed that the trend amongst more people globally is changing from illness to wellness.

Effect

Potential Cure

Eyes and vision

Retinopathy – caused due to oxidative stress and inflammation

Cataract- does not prevent but delays its occurrence.

Curcumin

Feet and skin

Foot ulcers.

Polyherbal formulation (on going R&D at Konark)

Joint pain – osteoarthritis

Osteoporosis-

Curcumin , curcumin + Ashwagandha

Oral

Gum diseases

Curcumin , curcumin + neem

Curcumin in the form of THC

Dry mouth

Anti bacterial effect of curcumin

Gingivitis

Antibacterial effects of curcumin

Complications

Alzheimer's disease

Curcumin, *Melissa officinalis*, *ashwagandha*, *tinoprora cordifolia*

Cancer

Prostate cancer

Breast Cancer

Colon Cancer

Curcumin

Cholesterol

Metabolic syndrome

Curcumin

UTI

Curcumin + *boswelina* – antibacterial activity

Further work remaining in the project:

Potential launch of product for various diseases

Speaking with the experts

SWOT analysis

Marketing strategies – 4Ps

Barriers to entry and overcoming challenges

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