CHAPTER 1

Overview on Herbal Product Regulations: Challenges and Solution

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Introduction

There is rapid growing demand of medicinal and aromatic plants in pharmaceutical, cosmetic, agriculture and nutraceutical sector. The sector is currently engaged in a modernisation and standardisation process aiming at an increase of its market share, while trying to meet the demand to deliver better quality herbal products. To ensure both safety and efficacy of herbal medicines, implementation of and adherence to guidelines and regulations specific to step must be followed.

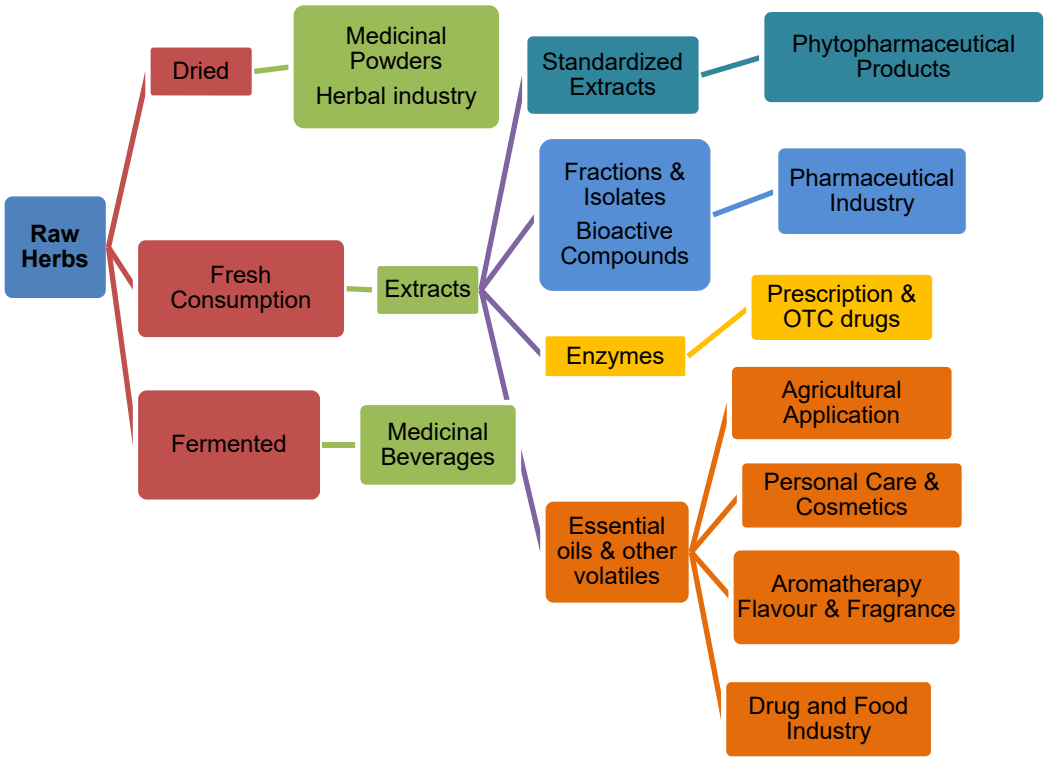

Figure 1.1 Potential Market Herbs derived Products.

Herbal products related terminologies in different parts of World		
Official terminology of Country	**Terminology**	**Definition**
United States	Dietary supplements	In the USA, the term dietary supplements are legally defined for the product "The Federal Food, Drug, and Cosmetic Act defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances

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Herbal products related terminologies in different parts of World		
Official terminology of Country	**Terminology**	**Definition**
		Unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. That means supplements should not make claims, such as “reduces pain” or “treats heart disease.” Claims like these can only legitimately be made for drugs, not dietary supplements. Dietary supplements include such ingredients as vitamins, minerals, herbs, amino acids, and enzymes. Dietary supplements are marketed in forms such as tablets, capsules, softgels, gelcaps, powders, and liquids”.
	Functional food	There is no defined and legal terminology, however, it is used as an alternative term for the ‘nutraceutical,’ with the concept that foods can have some health benefits. Functional food can be an extract, powder, or other processed forms originated from normal food such as gapes and peanuts that contain resveratrol with antioxidant properties. Health Canada has the definition of ‘nutraceutical,’ and is considered as the product originated from the food. In the EU legislation, “functional foods” or “nutraceuticals” are not recognized categories.
Japan and China	Health food	Japan and China mainly use the term health food, but with different regulatory processes. The general concept of health food is that the food contains nutrient as well as health benefits. Thus, some permitted health-related claims can be made. In Japan, health and nutrition claims handled separately, processing via different regulatory route while, in China, the claims are restricted to the pre-defined twenty-seven health claims.
Canada	Natural Health Products	Natural Health Products (NHP) is the category created for a variety of products that are naturally sourced products intended for improving human health. This is well defined in Canada and contains a variety of products like vitamins, minerals, herbal and homeopathic medicine and traditional medicines (e.g., Traditional Chinese Medicine).
	Food supplement	These foods are packed with nutrients or other substances with a nutritional or physiological effect, and mainly contained in the concentrated form and available in specific dosage form to supplement the normal diet. Food supplements can bear approved nutritional and health claims, but medical claims are not permitted. Food supplements are defined in EU as food and monitored through centralized legislation.
EU, Canada, Australia	Novel food	Novel food is mainly defined in EU and Canada and Australia, to deal with the category of the food that was not consumed as food historically in that region. Certain alterations to the regular food could be considered as novel food such as using new technologies or production processes (e.g., bioengineering, nanotechnology, or UV treated food, etc.), or upgraded with the addition of nutrients, or used the new sources for known products.
Australia	Complementary medicine	It is mainly used in Australia as a regulatory term. It denotes to all the health care practices that are not conventional part of a country's health care practices. Health care system from those countries is not integrated with these practices.

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Herbal products related terminologies in different parts of World		
Official terminology of Country	**Terminology**	**Definition**
	Traditional medicine	These are practices that have a long history of usage in particular jurisdiction. The practice could be a combination of beliefs, knowledge, and skills in addition to medicine. It could be used for preventative, diagnosis, or treatment of physical and mental health.
China	Traditional Chinese medicine (TCM)	It is part of ancient Chinese healthcare system. This system includes medicines, practices, acupuncture, massage and have preventative health as well as restoring the health. The medicines can be single herb, complex combination from plant or animal origin. Some of the cases prescribed by the health care practitioner. TCM are still integral part of Chinese healthcare system with hospitals and health care practitioners are there to monitor as well as prescribe the medicine or combination of therapy to the patients.
Japan	Kampo medicine	It is popular in Japan and derived from the ancient version of Traditional Chinese Medicine. Although Kampo medicine and TCM share a similar philosophy, the ingredients are different. Specifically, Kampo medicine has evolved and modified to incorporate materials from Japanese origin.
India	ASU drugs - Ayurveda, Siddha, Unani, Drugs	ASU drugs include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease or disorder in human beings or animals exclusively in accordance with the formulae described in the authoritative books.
UAE	Product derived from plant origin [traditional herbal medicine]	"Product derived from plant origin is a finished labelled medicinal product that contains as active ingredients aerial or underground parts of plants, or other plant materials or combinations thereof, where in the crude state or as plant preparations intended for prophylactic or therapeutic or other human health benefits" "Plant preparations are herbal ingredients present in a form other than the crude medicinal plant material including powdered plant material, balsams, dried and fluid extracts, tinctures, essential oils etc., prepared from plant material, and plant preparations obtained by fractionation, purification or concentration, without chemically defined isolated constituents regardless of whether or not its therapeutically active constituents have been identified"

Various Regulatory Guidelines for Herbs and Derived Products

Regulatory bodies are agencies which look after implementation of the legislation related to safety, efficacy and quality of drugs. They work under the Ministry of Health and Family Welfares. Each country has its own regulatory body. WHO (World Health Organization) and ICH (International Conference on Harmonization) are some important organizations who

proposed guidelines for the Quality Standards of Herbal products. Following are various guidelines for herbs and derived products:

Various Regulatory Guidelines for herbs and derived products are as follows:	
WHO Traditional and Modern Herbal Products	• WHO - General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine 2000 • WHO Guidelines for Assessment, Evaluation of Toxicity, Safety and Efficacy of Herbal Medicines 2000 • WHO Good Agricultural and Collection Practices [GAP, GCP, GACP] 2003 • WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems 2004 • WHO Guidelines for assessing quality of herbal medicines with reference to contaminants and residues 2007 • WHO Guidelines for Quality control of herbal materials 2011 [Updated edition of Quality control methods for medicinal plant materials, 1998] • WHO Guidelines for Selecting Marker Substances of Herbal Origin for Quality Control of Herbal Medicines 2017 • WHO guidelines on Good Herbal Processing Practice for Herbal Medicine 2018
AYUSH, India (Traditional Medicines)	• NMPB Guidelines and Standards for Good Field Collection Practices for Indian Medicinal Plants 2009 • AYUSH General Guidelines for Safety/Toxicity Evaluation of Ayurvedic Formulations 2018 • AYUSH Guidelines of Good Clinical Practices 2018 • General Guidelines for Drug Development of Ayurvedic Formulations, 2018
CDSCO, India (AYUSH and Modern herbal Products)	• Drug and Cosmetics Act, 1940. • Drug and Magic Remedies Act, 1954. • Narcotic Drugs and Psychotropic Substances Act, 1985. • CDSCO Guidelines of Good Clinical Practices 2013
Other acts, India	• Industries (Development Regulation) Act 1951. • Trade and Merchandise Marks Act 1958. • Indian Patents and Design Act 1970. • Factories Act 1948. • Indian Forest Act 1927 • Wild Life Protection act, 1972 • Geographical Indications of Goods (Registration and Protection) Act, 1999 • Biodiversity Act, 2002
ASEAN	• ASEAN Guidelines on Labeling Requirements for Traditional Medicines, 2015 • ASEAN Guidelines on Stability Study and Shelf-Life of Traditional Medicines, 2013

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Various Regulatory Guidelines for herbs and derived products are as follows:	
Nutraceuticals	• Food Safety and Standards act, 2006 • Dietary Supplement Health and Education Act of 1994 [DSHEA]
Cosmetics	• Drug and Cosmetics Act, 1940. • BIS/ISI Regulations

Global Overview of Regulations of Herbs and Derived Products

In 2003, a global survey of international health authorities indicated that most responding member 92 countries had regulations covering herbal medicines, whereas 85 countries reported having a registration system for herbal medicines.

Comparison of regulatory requirements when natural products are classified as "SUPPLEMENT"			
Country	**Regulatory Agency**	**Classified as Supplements**	**Regulatory Requirements**
USA	Dietary Supplement Health and Education Act (DSHEA) 1994	**Dietary Supplement - Center for Food Safety and Applied Nutrition (CFASN)/FDA** • Herbs/Botanicals • Vitamin • Minerals • Amino Acids • Dietary substance for use by man to supplement the diet by increasing the total intake • Concentrate, metabolite, constituent, extract or combination of the preceding substances.	➢ **Allowed route of admin- Oral only** ➢ **Pre-market approval - no** ➢ **Therapeutic claims- no** ➢ **Recommended dosing - yes** ➢ **Addition of new compound-Via NDI Notification***
Australia	Food Standards Australia New Zealand (FSANZ)	**Novel Food** • Foods and extracts from plants, animals, etc., • Foods and their extracts resulting from production processes and practices, and new technologies.	➢ **Allowed route of admin- NA** ➢ **Pre-market approval-NA** ➢ **Therapeutic claims- NA** ➢ **Recommended dosing- NA** ➢ **Addition of new compound-NA**
New Zealand	New Zealand Ministry for Primary Industries (MPI)	**Supplemented food** • Foods modified or with added substances so that they perform a physiological role	**Allowed route of admin- Oral only** ➢ **Pre-market approval-No** ➢ **Therapeutic claims-No** ➢ **Recommended dosing- If Supplemented food- no; If Dietary supplements- yes** ➢ **Addition of new compound-Active ingredient must be listed on website**
New Zealand	New Zealand Medicines and Medical Devices Safety Authority (Medsafe)	**Dietary supplements**	

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Comparison of regulatory requirements when natural products are classified as "SUPPLEMENT"			
New Zealand	Food Standards Australia New Zealand (FSANZ)	**Novel Food** • Foods and extracts from plants, animals, etc., • Foods and their extracts resulting from production processes and practices, and new technologies.	
China	China Food and Drug Administration (CFDA)	Health foods	➢ Allowed route of admin- Oral only ➢ Pre-market approval- yes ➢ Therapeutic claims- Only from one of 27 predefined ➢ Recommended dosing -yes ➢ Addition of new compound-Apply for registration and show toxicity data
Japan	Ministry of Health, Labor and Welfare (MHLW) for Medicines Consumer Affairs Agency (CAA) for Supplements	Health foods	➢ Allowed route of admin- Oral only ➢ Pre-market approval- no ➢ Therapeutic claims- FOHU and FFC can have health claim ➢ Recommended dosing- yes ➢ Addition of new compound- Needs to go through the registration process
EU Member States	**National competent authorities European Food Safety Authority (EFSA) if centralized procedures apply**	**Substances with a nutritional or physiological effect (vitamins, minerals, botanicals, etc.)**	➢ **Allowed route of admin- Oral only** ➢ **Pre-market approval- Only if considered as "novel foods" safety assessment by EFSA** ➢ **Therapeutic claims- No** ➢ **Recommended dosing- yes** ➢ **Addition of new compound- Apply for registration**
India	**FSSAI**	**Eight categories of Functional foods, namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods.**	➢ **Allowed route of admin- Oral only** ➢ **Pre-market approval- Only if considered as "novel foods" safety assessment by EFSA** ➢ **Therapeutic claims- No** ➢ **Recommended dosing- yes** **Addition of new compound- Apply for registration**

Comparison of regulatory requirements when natural products are classified as "MEDICINE"			
Country	**Regulatory Agency**	**Classified as Medicines**	**Regulatory Requirements**
United Kingdom	Food and Drug Administration (FDA)	Botanical Drug Products	➢ Pre-market approval- yes ➢ Clinical trial data- yes ➢ Therapies- Medicine only ➢ Reported adverse reactions/poisonings- yes ➢ Historical usage- yes
	Medicines and Healthcare products Regulatory Agency (MHRA) Committee on Herbal Medicinal Products (HMPC) Traditional Herbal Registration Scheme (THRS).	Complementary and alternative medicine	➢ Well-established use (marketing authorisation) and traditional use (simplified registration)
USA	Food and Drug Administration (FDA)	**Botanical drugs - Center for Drug Evaluation and Research (CDER)/FDA**	➢ Pre-market approval- yes ➢ Clinical trial data- yes ➢ Therapies- Medicine only ➢ Reported adverse reactions/poisonings- yes ➢ Historical usage- yes
Australia	Therapeutic Goods Administration (TGA)	**Complementary Medicines - Complementary and OTC Medicines Branch/TGA** • Herbs • Vitamin • Minerals • Nutritional supplements • Homeopathy • Microorganism (whole extracted) etc.	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes ➢ Therapies- Medicines Homeopathy Aromatherapy ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes
New Zealand	Food Standards Australia New Zealand (FSANZ)	**Herbal Remedies**	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes ➢ Therapies- Medicine Only ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes
Canada	Health Canada (HC)	**Natural Health Products** • Traditional medicine • Herbal Medicine • Homeopathy	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes ➢ Therapies- ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes

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Comparison of regulatory requirements when natural products are classified as "MEDICINE"			
Country	**Regulatory Agency**	**Classified as Medicines**	➢ **Regulatory Requirements**
China	China Food and Drug Administration (CFDA)	Traditional Chinese Medicine	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes ➢ Therapies- Medicine and Procedure ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes
Japan	Ministry of Health, Labor and Welfare (MHLW) for Medicines Consumer Affairs Agency (CAA) for Supplements	**Kampo Medicine**	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes ➢ Therapies- Medicine and Procedure ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage-
EU	European Medicines Agency (EMA)	**Herbal Medicinal Products** National competent authorities of EU Member States	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes/No ➢ Therapies- Medicine Only ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes
India	Drugs and Cosmetics Act, 1940 Drugs and Cosmetics Rules, 1945	**ASU drugs** -Ayurveda, Siddha, Unani, Drugs	➢ Pre-market approval- Yes ➢ Clinical trial data- Yes/No ➢ Therapies- Medicine Only ➢ Reported adverse reactions/poisonings- Yes ➢ Historical usage- Yes

Challenges in Herbs and Derived Product Regulations

Global promotion and acceptance of traditional as well as herbal medicines are facing following various challenges mainly in developed nations despite of promising evidence-based history.

Raw Material Standardization	Selection, identification, reproducibility, inter/intra species variation due to environmental factors, plant part used, time of harvesting, post harvesting factors, contaminants, pesticides, fumigants and toxic metals are the factors responsible for quality raw material. Poor cultivation and collection practices, lack of pre and post-harvest processing techniques, adulteration, misidentification of plant, faulty collection and preparation are major hurdles to get quality raw materials. Major percentage of medicinal plant raw materials from natural sources is creating environmental and social issues and affecting biodiversity. Poor implementation of

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	Good collection practices as well as *in situ* and *ex situ* conservation strategies is another problem for sustainable, socio-culturally equitable and safe supply of herbal drugs. Biodiversity, scarcity and conservation of raw material issues are causing the hinder in the availability of quality raw material.
Finished products standardization	***"Only quality raw material/s can give quality finished product/s.***" Poor implementation and regulation of the quality control guidelines in small and medium scale industries especially evaluation of pesticide residue, trace metal content, microbial and aflatoxins contamination leading to poor efficacy of herbal products.
Inadequate research and modernization	Decisive gap in traditional *and modern herbal drug research with reference to* pharmacokinetics studies, pharmacovigilance (toxicity, assessment of adverse reactions and drug-food interactions), active constituents-based monographs, clinical trials to endorse safety and efficacy
Skilled personnel and Infrastructure Development	Unethical practice of herbal medicine by non-qualified health workers responsible for exposure of unreliable and misleading information. Unregulated irrational practice of herbal drugs due to lack of trained personnel is major obstacle all around the world. Lack of knowledge of Intellectual Property Rights (IPR) of traditional medicines and modern herbal drugs with reference to biodiversity and biopiracy are creating confusions and demotivation in herbal drug research. Infrastructure facilities for processing, sophisticated modern analysis, manufacturing and research are not sufficient.
Fragmentation of the industry	Traditional medicines, modern herbal products, nutraceuticals and herbal cosmetics have different quality, safety, efficacy, labeling and marketing standard requirements at local, national and international levels lead to poor control and compliance for global commercialization of herbal raw materials.
Regulations	Lack of uniform regulations, stringent control, proper monitoring along with absence of focused marketing and branding creating chaos in herbal industry. There is especially a great confusion between regulations of traditional medicines, modern herbal products, nutraceuticals and herbal cosmetics.

Regions, category of registration of herbal products and their regulatory hurdle

Region	Category of registration	Major regulatory hurdle
ASEAN	1. Traditional herbal medicines 2. Indigenous herbal medicine. 3. Modified herbal medicine 4. Imported products with a herbal medicine base	1. Country-wise different National regulation 2. Product category is based on sample dossier. 3. Certain markers closely associated with a plant restricted by Health Sciences Authority, Singapore 4. Many categories of registration
Canada	1. Natural Health Product	1. Herbal products are not allowed as herbal medicine. 2. Single category as Natural Health Product 3. No scope to file as traditional herbal medicine.

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USA	1. Dietary supplement 2. Botanical drug	1. No therapeutic claims is allowed for dietary supplements 2. Botanical drug are under New drug application (NDA)
Europe	1. Traditional use registration 2. Well-established use marketing authorization 3. Stand-alone or mixed application 4. A simplified registration	1. 30 years Rule (15 +15 years) to qualify for well-established use – Traditional Herbal Medicinal Product (THMP) 2. EU GMP approved manufacturing / Research and development laboratories. 3. Stringent heavy metal / microbial contamination control. 4. Well established identified principle active marker control.
UK	1. Traditional herb registration (THR)	1. Evidence of quality as per the GMP standards 2. Evidence of safety and efficacy based on long traditional use of 30 years overall and 15 years in EU, 3. The label should carry that the THR certification mark and a statement that the product is “exclusively based on long term use”. 4. For major health claims, or the products that calls for a medical prescription, 5. Market Authorization is required.
India	1. Traditional herbal medicines 2. Indigenous herbal medicine. 3. Modified herbal medicine	1. Evidence of safety and efficacy based on traditional texts 2. Many categories of registration 3. Must follow Drug Controller General of India (DCGI's) regulations

Solutions in Herbs and Derived Product Regulations

- Uniform herbal drug registration process, dossier submission, pharmacopoeias, related policies and regulations for ensuring uniformity in quality, safety, and efficacy of the one herbal product globally
- Biodiversity and traditional knowledge should be major control factors for herbal product marketing.
- Geographical location-based group farming, strengthening of indigenous techniques of cultivation, buy-back process, promotion of value-added products, industry tie-ups for medicinal plant cultivation should be encouraged to get quality raw material.
- Quality propagation material in consideration to therapeutic efficacy and safety should be get available from certified regional facilitation centers.
- Although medicinal and aromatic plants have been used for thousands of years, basic research programmes and administrative actions need to be focused on the quality raw material supply. To control raw material contamination and maintain uniformity in raw materials of different locations, it is necessary to implement standard operating

procedures (SOPs) for collection, cultivation and processing of medicinal plants and derived value-added products.

- Knowledge of cultivation, collection, pre- and post-harvesting techniques, IPR and marketing strategy and latest developments and policies related trainings of herbal raw material can be shared by participatory learning among cultivars, growers, traditional healers, researchers and manufactures.
- Proper implementation of uniform regulations, development of more elaborate guidelines on quality control and quality assurance aspects, and development of marker-based standards are needed to produce safe and effective herbal medicines.

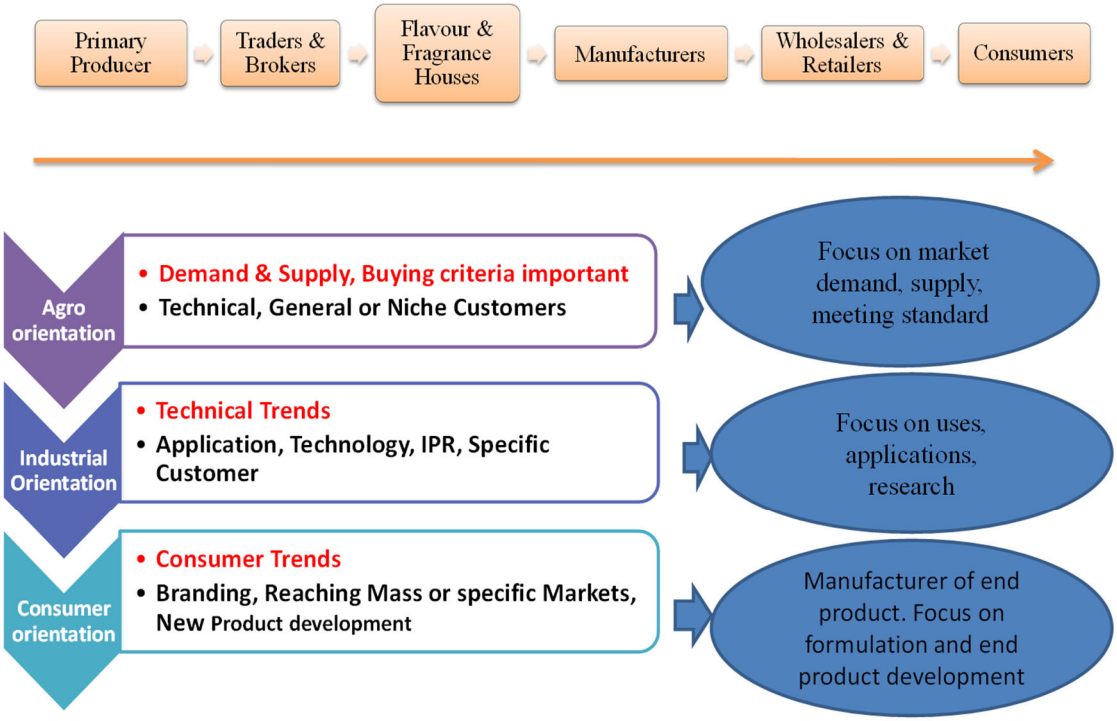

Figure 1.2 Solutions in Herbal Product Regulations.

Further Reading

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- National policy on traditional medicine and regulation of herbal medicines-

National policy on traditional medicine and regulation of herbal medicines : report of a WHO global survey

- International Regulatory Cooperation for Herbal Medicines (IRCH)-

International Regulatory Cooperation for Herbal Medicines (IRCH) (who.int)

- Herbal medicinal products-

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