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REGULATORY AFFAIRS IN AYURVEDA AND SURVEY

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ABSTRACT

The field of Ayurveda, one of the oldest systems of traditional medicine, has witnessed significant global growth in recent decades. With increasing commercialization and international acceptance, there is a rising need to align Ayurvedic practices with modern regulatory frameworks to ensure safety, efficacy, and quality of products. Regulatory affairs in Ayurveda involve compliance with national and international laws, including product registration, labeling, clinical validation, and good manufacturing practices (GMP). In India, the Ministry of AYUSH plays a central role in regulating Ayurvedic medicines, while internationally, products often face scrutiny under the laws of countries where traditional medicine is not formally integrated.

This study aims to provide an overview of the current regulatory landscape governing Ayurveda and presents findings from a survey conducted among Ayurvedic practitioners, manufacturers, and regulatory professionals. The survey explores awareness levels, challenges faced in regulatory compliance, and perspectives on harmonization of traditional and modern health regulations. Results reveal key gaps in knowledge, limited access to regulatory resources, and a strong demand for updated training programs. The findings underscore the need for enhanced policy frameworks and stakeholder education to foster safe, effective, and compliant growth of the Ayurvedic sector.

KEYWORDS: *Regulatory Affairs, Worldwide, Regulatory Agencie, Ayurveda, Naturopathy,Unani, Siddha, Homeopath*

INTRODUCTION

This review highlights the regulatory status of herbal medicines in India and in specific countries. The herbal medicines are being used in different system of medicines like the Ayurveda, siddha, homeopathy, unani and Chinese system of medicine. The regulatory authorities and WHO are making efforts to collaborate in order to for a harmonized herbal medicine regulation. The Drugs and Cosmetics Act 1940 and Rules 1945 consist of the regulatory guidance and guidelines for Ayurveda, Unani, Siddha medicine. The herbal medicines are being categorized as Complimentary medicines, Natural health products, Prescription medicines, over the counter medicines, Supplements, Traditional herbal medicines globally.

Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way and also is to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities.

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods) most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals Ayurveda is one of the most renowned traditional systems of medicine that has survived and flourished from ages till date. With the enormous knowledge of nature based medicine, the relationship of human body constitution and function to nature and the elements of the universe that act in coordination and affect the living beings, this system will continue to flourish in ages still to come

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There are many avenues still to be explored by the researchers, practitioners and experts in the field who carry the responsibility of keeping the traditional systems of medicine (TSMs) alive and contributing to their growth in the future. However, due to many barriers such as lack of literature sources in different languages and insufficiency of awareness about the basic principles and histories of the systems from different ethnic origins, there is a lacuna of exchange of information from systems around the globe. Knowledge of systems from different ethnic origins would bring about interchange of knowledge and increase the understanding of different systems, and this can ultimately contribute to integration and advancement of herbal drug research when accompanied by collaborative work of researchers from different countries. These futuristic goals can be accomplished when one gains insights about the systems, the principles and histories and works upon the strengthening aspects common between the various TSMs. In this review, we have made an attempt to put forth the basic principles of doctrine and history of Ayurveda to contribute to the above said perspectives.

1. STATEMENT OF PROBLEM

Despite the growing popularity and recognition of Ayurveda as a traditional system of medicine, the regulatory framework governing its practice, products, and commercialization remains fragmented and inconsistent across regions. In many countries, including India—the birthplace of Ayurveda—there is a lack of uniformity in standards for quality control, safety assessment, and clinical validation of Ayurvedic formulations. This has led to concerns about the credibility, safety, and global acceptability of Ayurvedic products. Moreover, limited data is available on the awareness, understanding, and compliance levels among stakeholders, including manufacturers, practitioners, and consumers, regarding existing regulatory policies. Without a clear and enforced regulatory structure, the risks of adulteration, false claims, and misuse persist. Therefore, it is essential to conduct surveys and gather empirical data to evaluate the current state of regulatory awareness and implementation in the Ayurvedic sector, in order to identify gaps and recommend improvements that support both public health and the sustainable development of the industry.

2. HYPOTHESIS

The increasing global acceptance of Ayurveda has highlighted the urgent need for a robust and harmonized regulatory framework to ensure the safety, efficacy, and quality of Ayurvedic products. While traditional systems like Ayurveda are deeply rooted in cultural heritage, their integration into modern healthcare systems requires compliance with national and international regulatory standards. However, current regulations vary significantly across countries, leading to inconsistencies in product approval, labeling, and marketing. A survey-based study exploring the perceptions of Ayurvedic practitioners, manufacturers, and regulatory authorities can help identify key gaps in the existing regulatory landscape. The hypothesis is that a lack of standardized regulatory policies and limited awareness among stakeholders hinder the effective global integration and commercialization of Ayurvedic medicine. Understanding these challenges through empirical surveys can guide the development of comprehensive guidelines and support evidence-based policymaking in the Ayurvedic sector.

3. OBJECTIVES OF REGULATORY AFFAIRS IN AYURVEDA

1. How and why the pharmaceutical industry and drug regulations have developed in USA Major Regulations of USA
2. Framework of EU and its regulatory

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3. "The Rules Governing Medicinal Products in the European Union"
4. Pharmaceutical Legislations of EU
5. Indian Pharmaceutical Industry & Drug Regulations development in different Era.

4. HISTORYOFREGULATORY AFFAIRS IN AYURVEDA

Ayurveda has an age old history since the 2nd Century BC. Ayurveda has its foundations laid by the ancient schools of Hindu Philosophical teachings named Vaisheshika and the school of logic named as Nyaya. It is also related to the manifestation framework, well-known as Samkhya, and it was established in the same period when schools of Nyaya and Vaisheshika flourished

The Vaisheshika School preached about inferences and perceptions that should be obtained about a patient's pathological condition for treatment. Whereas, Nyaya school propagated its teachings on the basis that one should have an extensive knowledge of the patient's condition, and the disease condition before proceeding for treatment. The school of Vaisheshika, classifies the attributes of any object into six types: substance, particularity, activity, generality, inherence and quality called as Dravya, Vishesha, Karma, Samavaya Samanya, Guna and respectively. in Sanskritlanguage 2, 3 Later, Vaisheshika and Nyaya schools worked together and jointly founded the nyaya-vaiśesika school. The nyaya-vaiśeşika school, in the later years brought glory to the ancient knowledge and helped in disseminating the knowledge about Ayurveda.

Even before these schools were established and also today, the origin of Ayurveda is considered to be divine, from the Hindu God, Brahma who is called as the creator of the universe. 4. 5 It is believed that the creator of the universe passed on this holistic knowledge of healing onto the sages for the well-being of mankind. From the sages the knowledge of traditional medicines was passed on to the disciples and then to the common man by various writings and oral narrations. The information about the healing properties of the herbs was composed in the form of poems, called "Shlokas". These were used by sages to describe the use of medicinal plants. The Hindu system of healing is believed to be based on four eminent compilations of knowledge (Vedas) called as Yajur Veda, Rig Veda, Sam Veda, and Atharva Veda. The Rig Veda is the most well-known of all the four Vedas and describes 67 plants and 1028 Shlokas. The Atharva Veda and Yajur Veda describe 293 and 81 medicinally useful plants. The practice of Ayurveda is based upon the knowledge gained from these Vedas.

The writings in Rig Veda and Atharva Veda are attributed to "Atreya" who is believed to have been conferred with this knowledge from Lord Indra, who initially received it from Lord Brahma. Agnivesha compiled the knowledge from the Vedas, and it was edited by Charaka and some other scholars and is presently called as "Charaka Samhita". Charaka Samhita describes all aspects of Ayurvedic medicine and Sushruta Samhita describes the Science of Surgery Both these legendary compilations are still used by practitioners of traditional medicine. These ancient texts are available in various translations and languages like Tibetan, Greek, Chinese, Arabic and Persian. There are several other allied minor compilations like Nighantu Granthas, Madhava Nidana and Bhava Prakasha from the contributions of various scholars, however Charaka Samhita is the most respected of all the records

5. WHAT IS REGULATORY AFFAIRS

It is a unique mix of science and management to achieve a commercially important goal within a drug development organization. Touches everything relating to drugs from the earliest non-clinical studies, through development, into routing manufacture and marketing, can add significant impact for patients and drug companies,

5.1) WHY IS REGULATORY AFFAIRS NEEDED

Drug development and commercialization is highly regulated the path to drug registration Marketing Approval) is paved with good intention but can be complicated Things change constantly.

5.2) PARAMETER OF REGULATORY AFFAIRS

Design = Development Plan
Construction = Assembling & Submission Management
Testing = Where are the weaknesses
Co-ordination = Writing/reviewing, supervising National Laws (e.g. UK - Medicines Act, US-CFR) Page-4
Drug regulations
Regional Laws (EC directives)
National and Regional Guideline

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5.3) REGULATORY BODIES IN THE WORLD

Table 1: Different regulatory bodies in the world

Country	Regulatory Body
USA	Food and Drug Administration (FDA)
UK	Medicine and Healtrhcare Product Regulatory
Australia	Therapeutic Goods Administraction (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Japan	Ministry Of Health, Labour & Warfare (MHLW)

6. HISTORICAL OVERVIEW OF REGULATORY AFFAIRS IN AYURVEDA:

During 1950s, multiple tragedies i.e. sulfonamides elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMP

6.1.AYUSH SYSTEM

AYUSH is an acronym for Ayurveda, Yoga & Naturopathy, Unani, Siddha, Homoeopathy and Sowa Rigpa. Ayurveda is the oldest system with a documented history of its practice for more than 5000 years whereas Homocopathy is in practice in India for around 100 years. These systems are being practised in the country with diverse preferences of people and infrastructural facilities. AYUSH systems of medicine include Indian systems of medicine and Hopmoeopathy.

1. Ayurveda: Ayurveda is the time tested traditional system of medicine of India that explains the cause of different miseries, imparts the knowledge of life and advocates promotion of physical, mental and spiritual wellbeing. It is believed that Ayurveda is originated out of Vedas (particularly Rigveda and Atharvaveda). Numerous references of health, diseases, their treatment as well as use of non-materialistic things such as sun rays, fasting, mantra etc; are available in these Vedas. The knowledge of Ayurveda was first comprehensively documented 3 in the compendia like Brahma Samhita", Agniveshatantra, Susrut Samhita", Bhela Samhita" etc.

2. Unani: Unani system of medicine is a comprehensive medical system, which provides preventive, promotive, curative and rehabilitative health care. The system is holistic in nature and takes into account the whole personality of an individual rather than taking a reductionist approach towards disease. The fundamentals, diagnosis and treatment modalities of the system are based on scientific principles.

3. The basic framework of this system is based on the Hippocratic theory of four Humours, according to which any disturbance in the equilibrium of humours causes disease and therefore the treatment aims at restoring the humoral equilibrium. The system also believes that Medicatrix Naturae (TabiatMudabbira-iBadan) is the supreme power, which controls all the physiological functions of the body, provides resistance against diseases and helps in healing naturally.

4. Siddha: The Siddha system is ancient system of medicine in India. The Siddha system medicine is found by eighteen Siddhers namely Agasthiyar, Thirumoolar, Bogar, Pathanjali, Pulipani etc., the eighteen Siddhers had contributed towards the systematic development and recorded in Tamil language.

5. Yoga: The word "Yoga" comes from the Sanskrit word "yuj" which means "to unite or integrate." Yoga is about the union of a person's own consciousness and the universal consciousness. It is primarily a way of life, first propounded by Maharshi Patanjali in systematic form Yogsutra. The discipline of Yoga consists of eight components namely,
restraint (Yama), observance of austerity (Niyama), physical postures (Asana), breathing control (Pranayam), restraining of sense organs (Pratyahar), contemplation (Dharna). meditation (Dhyan) and Deep meditation (Sumadhi).

6.2. REGULATION AND QUALITY CONTROL OF ASUH&DRUGS

Drug Control Cell of the Ministry oversees the enforcement of regulatory and quality control provisions for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs. The Cell coordinates with Central Drug Standards Control Organisation (CDSCO) the State Licensing Authorities and Drug Controllers to achieve uniform administration of the provisions of Drugs & Cosmetics Act, 1940 and Rules and Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules for providing regulatory guidance, direction and clarification pertaining to ASU&H drugs.]

7. IMPORTANCE OF REGULATORY AFFAIR

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company. Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many

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millions of Euros or dollars, pounds, to develop and even a three month delay in bringing it to the market has considerable financial considerations.

7.1.REGULATORY AFFAIRS IN PRODUCT MANAGEMENT:-

The key role of RA professional is broader than registration of products, they advise companies both strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing strategies.

7.2. REGULATORY AFFAIRS IN CLINICAL TRIALS:-

The RA professional is the primary link between the company and worldwide regulatory agencies such as US Food and Drug Administration (USFDA & Center for Devices and Radiological Health) Medicines and Healthcare Products Regulatory Agency, United Kingdom, (UKMCA), Therapeutic Goods Administration, Australia European Medicines Agency.

Organization of Economic Collaboration and Development (OECD) and Health Canada.

He also communicates and interprets the seemingly endless mace of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and presents finding of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules. At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public. Operationally RA is responsible for assuring that government obligation, market driven demands and evolving scientific conventions are understood and addressed by various stakeholders

7.3 REGULATORY AFFAIRS IN R&D

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags

8. WORKING OF REGULATORY AFFAIRS INFORMATION

Regulatory is the interface between the company/sponsor and the outside world the regulatory department is a focal point of information, both incoming and outgoing. In order to practice regulatory and succeed, both in objective public measures (e.g., approvals) and internal ones (eg, recognition and reward), etc.

8.1. GATHERING INFORMATION

All the information should be ethical proper documentation any opportunity to see, hears, or talks with a regulator, a more experienced drug development expert, a colleague, or a sworn enemy is an opportunity to gather information. There should be no need to go over published sources of information, both commercial and governinental.

8.2. COMMUNICATING INFORMATION

The easiest way information is to share and communicate is non-critical information. The main issue with such information is getting to the right audience without boring them into forgetting that they're getting useful data. Most companies subscribe to news updates or have internal regulatory information updates through email. One suggestion is to make them playful and user friendly, using popular Web pages as guides. The difficult information to communicate is critical information. This could mean anything vital to the success or failure of a project, specific and important feedback from the FDA. The first thing to do is document the information carefully, so that we can fully understand it and its implications 47

9. NEED OF REGULATORY AFFAIRS IN THE PHARMACY CURRICULUM

India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

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10. SURVEY AND FEEDBACK

1.(ANKYLOSING SPONDYLITIS patient)

Mr. Aditya, Hyderabad, Telangana, 19-03-2016

I have had AS (HLA B27+) for 22 years now. I am diagnosed when I was 10 and right now am 32. My Rheumatologist put me on NSAIDs (sulfasalazine) and as I grew, the disease took a toll on me and the dosage has been gradually increased and there came a saturation point where even pain killers weren't helping me. I was then put on modern expensive biologic -Enbrel and literally survived on it for close to 8 years. Over the years the disease affected my ankles, knees, hip, neck, shoulder, lower back, spine and not to forget the unbearable butt pain. There were days where I literally used to cry all alone unable to bear the pain and have had countless sleepless nights. The only saving grace was that none of the joints got fused as I tried maintaining an active and healthy lifestyle throughout. Swimming helped me big time.

I got to know about Charaka and Dr. Chandrasekhar through a friend and colleague of mine who himself got cured of Rheumatic Arthritis and I visited him in Oct'2015. I was never a firm believer of Ayurveda having tried allopathy for 22 years, homeopathy for 3 years and also naturopathy. Initially, I was apprehensive to try the Ayurveda regime – treatment and the diet having had a prior bad experience with naturopathy. But all my thoughts were brushed aside within a few days I started the treatment.

Chandrasekhar sir is very approachable, patient enough to hear all what I had to say and gave me enough belief that my life is going to change for good. He has such a wonderful team of trained therapists who made me feel at home during the course of the treatment. And I've been 100% true to prescribed diet since I started my treatment at Charaka and have undergone about 110 days of Panchakarma treatment.

At this point I am off of biologics for 5 months now – never before in my last 8 years and I am about 85-90% symptom free except for manageable neck and hip pain. It's been 2 months since I completed Panchakarma process and I feel that I am in the right path of symptomatic cure.

It is with deep sense of gratitude I thank Chandrasekhar sir and would strongly recommend Charaka to all those ailing from chronic diseases.

2.(SLIP DISC / SCIATICA patient)

Mr. Kumar, USA, 13-03-2025

My condition before treatment: I had a back pain which became severe after lifting some weights, I had pain in lower back as well as sciatica pain radiating in to my left leg and right shoulder. Dr Chandrashekhar did an accurate diagnosis and later MRI scan also confirmed a fairly large disc protrusion at l4-l5.

During Treatment: I had a 45 day Panchakarma treatment and medication. Dr monitored my progress and changed the medication accordingly throughout the treatment. After 2 weeks my pain reduced by about 20-30%, by 4th week I was better by 50%, I noticed a very good progress in 5th, 6th week of the treatment where I got 80 – 90% better and I could also sit comfortably without sciatica pain my leg.

After treatment: Two weeks after the treatment I am feeling 90% better and I feel confident about further improvement.
Overall Experience: I thank God for leading me to Charaka, I want to thank Dr. Chandrashekar for the treatment and I greatly appreciate his commitment towards improving the health of his patients. Also I want to thank the therapists and staff at Charaka every one were very helpful and committed. The facility is very clean and well maintained, all the oils and medication used during the treatment are of best quality, Thanks

3.(CERVICAL SPONDYLOSIS / CERVICAL SLIP DISC patient)

Mr. T V Bhaskar, Hyderabad, 22-08-2015

I have heard the phrase, 'health is wealth' umpteen number of times. It did not strike me until I was affected by a severe cervical spondylitis. At 40 years of age, I am relatively young for this disorder. I had been to many hospitals and a good number of doctors have told me that my condition was severe and that I had hurt my back badly. I developed the pain in 2013. I don't remember any particular instance of hurting my back. It was due to my life style. I used to work late and several times I used to sit long hours continuously at the computer and work. My MRI reports said that I had problems at C2, C3, C4, C5, C6 and C7. Physiotherapy, traction and medication could not help me, though they gave me some relief.

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As I was experimenting with different doctors, my friends suggested me to try Kerala Ayurveda. Initially I planned to go to Kerala and due to circumstances and time, I started searching for Ayurveda centres in Hyderabad. One of my friends suggested me to try Charaka Ayurveda at Secunderabad.

I am happy that I met Dr. Chandrashekar. He assured me that I was going to be alright and normal again. He suggested 45 days of treatment. Under his supervision I successfully completed the treatment. I feel great and feel normal again without any pain. I love sports and I slowly started playing football as well.

CONCLUSION

Today, the cost of health care is constantly rising, and affecting people's ability to afford health coverage. Drug-based medicines are being unaffordable for economically poor countries like India and problematic in the Western countries due to numerous side effects. The drug should be the last rather than first mean of treatment, beginning with the natural healing method like Ayurveda. One of the Ayurvedic treatment modalities such as Panchkarma can remove disease before its manifestation. Having all the above beauties, Ayurveda is still lagging behind because of the lack of scientific evidence in many cases and poor research methodology.

The development of guidelines for methodology in Ayurveda requires a huge professional work both by academicians and practitioners who must have the necessary knowledge and motivation for this task. Otherwise, Ayurveda will gradually lose its identity and will become a history of medicine. Although the process of research is time taking but it is the only way to overcome the difficulties in the promotion of Ayurveda worldwide. The work in a coordinated and well-organized manner with no bias can improve Ayurveda. Nevertheless, it also a bitter truth that modern researches have not been very rewarding for Ayurveda itself as most of these researches is being used Ayurveda to extend modern bioscience.

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