(vii) Practitioners who prescribe these medicines

(viii) The consumer

(ix) Exporters of herbal formulations

(x) The government

(xi) Multi National Pharma Companies

1.4.6 Each of the above players impacts the herbal sector in their own unique way. At one end of the spectrum are the beneficiaries like growers, collectors and manufacturers who have a stake in promoting the herbal systems as it is their livelihood, at the other end of the spectrum are large pharmaceutical companies who feel threatened by the ever expanding herbal market, which could impact sales of their own products. They have deep pockets and are not averse to using their national governments to impose non-tariff barriers, like excessive quality requirements, to import of herbal formulations from developing countries. Thus the stakeholders range from impoverished communities engaged in collection of herbs to the multi-millionaire MNCs, all of whom are responsible for impacting the quality of herbal drugs. How exactly each one does so will be examined in the succeeding chapters.

1.5 Statement of the Problem

1.5.1 There is a resurgence of interest in traditional medicine (TM) therapies the world over. Burdened as the people are with chronic disorders arising out of the stresses of modern day life for which modern medicine has no answers, humanity is looking towards "safer" treatment options based on natural products. According to

estimates the global market of traditional therapy was US $ 60 billion in 2002 and is estimated to touch US $ 5 trillion by 2050. According to the report of the World Health Organization (WHO), over 80% of the world population relies on traditional systems of medicines for their primary health care. India is well placed to take advantage of this revitalization of interest given the fact that we have an extremely sound traditional medicine knowledge system, coupled with state-of-the-art scientific capability to validate this knowledge.

1.5.2 Perhaps the biggest attraction of herbal remedies is that they are perceived to be safe and largely devoid of side effects. A good drug should be able to pass the tests of safety, efficacy and quality. The fact that Ayurveda is one of the oldest systems of healthcare and has not only survived to the present day but is witnessing a global revival, is proof enough of its efficacy and safety but the greatest challenge to widespread acceptance of Ayurvedic drugs remains quality. There are questions being raised on issues of contamination, heavy metal residues and microbial overload, sometimes even in reputed medical journals[1].This becomes even more important given the increasing consumer awareness. Consumers today are looking for products which would meet quality standards of the highest order. This encompasses the whole chain from raw material sourcing and product manufacturing to labeling and packaging. This work attempts to point out ways in which this can be tackled by analysing the loopholes which need to be plugged in the existing system.

1.5.3 There are 8896 manufacturing units[2] of ASU medicines in India. 80% of these are in the tiny sector with little wherewithal to invest in quality control mechanisms which would bring their products in line with even rudimentary quality standards leave alone globally recognized standards. There are only a handful of big players in the

sector who have the financial and technical capacity to produce quality products and invest in R&D efforts which are of paramount importance if the firms have to remain competitive in an increasingly diversified market. The standards for manufacture of these medicines are laid down in the Ayurvedic pharmacopoeias brought out by the department of AYUSH, Ministry of Health and Family Welfare, Government of India.

1.5.4 Further, in order to tap the huge potential provided by the overseas markets for natural products there is the additional requirement of meeting the quality norms of the importing countries. Different countries have laid down standards which are extremely stringent as compared to our domestic quality requirements. If we want a piece of the $5 trillion pie which we rightfully deserve for reasons already stated above, there can be no compromise on quality. Thus quality becomes the single most important factor in wider acceptance of the Indian Traditional Medicinal Systems.

1.6 Scope and limitations of the study

1.6.1 The officially recognized Indian systems of medicine (ISM) are, Ayurveda, Yoga, Unani, Siddha and Homoeopathy which are represented by the acronym AYUSH. Of these Yoga is a drugless system and does not prescribe medicines as such. Hence it is out of the scope of the current paper which deals with examining

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[1] Robert Saper, "Heavy Metal Content of Ayurvedic Herbal Medicine Products", The Journal of the American Medical association, 2994, 292 (23)

[2] AYUSH in India 2012, publication of Department of AYUSH

the issues of quality assurance of drugs used in ISM. This leaves us with Ayurveda, Unani, Siddha (ASU) and Homoeopathy. The latter is governed by different Rules under the Drugs and Cosmetics Act (DCA) while the former group of ASU is dealt together. This paper seeks to look at quality assurance of ASU medicines. Further since the lion's share of the total output of these medicines is contributed by the Ayurvedic system, the study narrows down to looking at the whole issue of quality assurance of ASU medicines through the prism of Ayurvedic medicines with cross references from the other two systems.

1.6.2 The general perception is that ASU Medicines are by and large substandard, typified by bad packaging with the labels giving little or no information about the ingredients, the expiry date, indications and contra-indications etc. To understand this we can look at the genesis of the Ayurvedic system itself. Ayurveda traditionally was a very personalized system of medicine where the vaidya diagonised symptoms, established a personal rapport with the patient and as per the "prakriti" of the person prescribed medicines, which were prepared either personally by him or under his guidance. In short he used to be the physician, counselor and manufacturer, all rolled into one. Juxtapose this with today's scenario, where the vaidya is replaced by clinically trained doctors who see patients by the dozen with little time for personalized medication and prescribe medicines which are manufactured in factories. Obviously the doctor is not responsible for the quality of the medicine which he prescribes. He has no control over the quality of ingredients which go into the medicine leave alone over the numerous processes that go into producing the final product.

1.6.3 In such a scenario it becomes obvious that not only should we have quality control procedures firmly in place but also the need to enforce these controls more effectively than is happening at present. Thus the main thrust of the study will be to assess the effectiveness of the present regulatory regime in assuring the quality of the Ayurvedic medicines and suggest appropriate changes in the same to assure the quality of Ayurvedic medicines and their acceptability both nationally and internationally.

1.6.4 The current regulations and enforcement mechanisms are ordinarily not entirely suited towards ensuring quality of these products, which could be one of the reasons preventing wider acceptability of the Ayurvedic system. The Regulations in India and some other countries will also be examined in so much as they impact the acceptability of the system.

1.7 Research Questions

In this background this paper seeks to arrive at answers to the following:

i. What are the factors affecting the quality of Ayurvedic medicines and wider acceptability of the system?

ii. Whether the current regulatory regime in India is adequate to deal with quality issues of Ayurvedic medicines or the enforcement mechanisms need to be strengthened to ensure better quality of products?

iii. What are the international regulations in countries having an impact on exports?

iv. What are the changes required in the existing law to ensure quality and acceptability of our traditional medicine systems worldwide?

1.8 Aims and objectives:

i. To study the problems related to assuring the quality of Aurvedic medicnies.

ii. To study the current regulations related to ensuring quality of Ayurvedic products and the enforcement mechanism thereof.

iii. Effect of quality on exports of Ayurvedic products to other countries

iv. To explore probable linkages between IPRs and Traditional Medicinal Knowledge holders.

v. To identify strengths and weaknesses of current policies and to suggest appropriate changes in policy and law to assure quality of Ayurvedic medicines.

1.9 Literature Review

Currently available Guidelines on quality of herbal drugs are :

- WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues
- Good Agricultural Practices published by the National Medicinal Plants Board
- Good Field Collection Practices published by the National Medicinal Plants Board
- Good Manufacturing Practices as given in Schedule T of the Drugs and Cosmetics Act, 1945 and rules 1948

- Ayurvedic Pharmacopoeia of India
- The Ayurvedic Formulary of India
- Robert Saper, "Heavy Metal Content of Ayurvedic Herbal Medicine Products", The Journal of the American Medical association, 2994, 292 (23)
- National Workshop on Quality Assurance of ASU drugs : Proceedings, Department of Ayush, 2008
- Kales SN, Saper RB. Ayurvedic lead poisoning : An under-recognized, international problem. Indian J Med Sci 2009;63:379-81
- Traditional Herbal Medicinal Product Directive (THMPD) of the European Union
- Documents of the Intergovernmental Committee constituted by the World Intellectual Property Office (WIPO) on Traditional Knowledge
- The Traditional Knowledge Digital Library of the Department of AYUSH and CSIR
- Voluntary Certification Scheme for AYUSH products by the Quality Council of India (QCI)

1.10 Methodology:

The study is empirical involving both primary and secondary data. The latter has been collected from reports, books. Articles etc. whereas the primary data has been collected with the help of questionnaires and interviews with different stakeholders. Consultations and discussions were held with, policy makers, regulatory authorities, industry, exporters, etc to gather their views. The data so collected has been analysed with a view to finding out the effectiveness of different regulations on quality of Ayurvedic products. A questionnaire was prepared after due consultation with

industry and was sent to manufacturers chosen at random. Responses have been received from 62 manufacturers. The data has been analysed and the results may be seen in annexure 2.

1.11 Chapterisation Scheme

Chapter1: Introduction

This chapter deals with the current status of Ayurveda in the world health scenario. How there is a resurgence of interest in this ancient science and what are the prospects for its future. The relevance of quality of Ayurvedic medicines in the context of global acceptance of Ayurveda has been discussed.

Chapter 2 : Ayurvedic Industry and its Quality Concerns

The biggest stakeholder in the manufacture of Ayurvedic drugs is obviously the Ayurvedic drug industry. The issues which are of immediate importance to this sector and the complex nature of relationships among various stakeholders has been analysed by using the systems thinking approach.

Chapter 3 : National and International Regulations impacting quality of Ayurvedic medicines.

An attempt has been made to suggest comprehensive changes required in the legal provisions in order to upscale quality of Ayurvedic medicines.

Chapter 4 : Quality of Medicinal Plants and its impact on quality of Ayurvedic Drugs

Medicinal plants constitute the main raw material for Ayurvedic medicines. Obviously then the quality of drugs has a direct relation to the quality of medicinal plants. Trade in Medicinal plants, the factors responsible for decreased availability of quality raw material, strengthening of the supply chain and other issues have been discussed in this chapter.

Chapter 5 : Intellectual Property Rights and Ayurvedic drugs

This chapter deals with the host of issues which arise out of the fact that Traditional Knowledge is by and large not patentable which in turn gives rise to obvious industry concerns about not being able to garner the benefits of investment into R&D efforts in the absence of patent rights.

Chapter 6 : Conclusion : suggested Policy Framework for Quality Assurance of Ayurvedic Drugs

Based on available literature and on the findings of the survey, certain suggestions have been made to assure quality of Ayurvedic Drugs. Some of these have been given in brief as they have been discussed in detail in the respective chapters for example the amendments which have been suggested to the Drugs and Cosmetics act, 1945 in order to make it more relevant to the emerging scenario of Ayurveda, are spelt out in great detail in chapter 3. Similarly increasing productivity along with protecting our national heritage of medicinal knowledge have been summarized in the last chapter but the ramifications of it have been discussed in detail in the Chapter on IPR.