

Global Market

Indian Subcontinent is supposed to be the biggest market for Homeopathy and the system is most popular here though the system originated in Germany. India is the country with largest number of homeopaths and in this country Homeopathy seems to be best integrated within the society. Germany, the US, France and United Kingdom are other foreign countries where Homeopathy is recognised as a system of medicine other than Indian Subcontinent. It has also started getting some response in developing countries like Argentina, Mexico and Ukraine and developed countries like Spain. No exact estimates for homeopathic market and its growth rate abroad can be made but it is felt that the trend has shifted towards Homeopathy due to the fear of side effect of allopathic medicine. This is evident from a chapter on alternative medicine in allopathic book "Reminton's Practice of Planning " which says that there is growing popularity in alternative medicine because of various reasons. Firstly due to its perceived, either potentially beneficial or pernicious, effects on individual health or society. Secondly, a high tech medicine does not care or pay attention to the patient's belief. Thirdly medical cost have increased fifteen fold in past thirty years with only 40% being served with adequate medical care. The global market scenario is appended as annexure 4(i.).

Currently, USA, Germany and United Kingdom are the countries to which India is exporting homeopathic product. India is also importing from these countries. Our major export destination of homeopathic products is Germany, which accounts for 90% to 95 % of our exports. For USA our exports have been increasing since 1992-93. Among developing countries where we export are Russia, Ukraine and Sri Lanka. In Russia 20% of medical care is based on the system of Homeopathy. Even for Sri Lanka the exports are increasing for the period starting 1992-93. Brazil is another country, which has just come into Indian export market.

The total exports of Homeopathic medicines from India are given as annexure 2.

US Homeopathic market

Annual sales of OTC homeopathic drug products in US are estimated to be over \$ 75 million and are increasing at annual rate of 15 to 20%. In US there are five schools and training centres for homeopaths, and at least 20 homeopathic pharmacies and four homeopathic organisations.

In December 1988 the Homeopathic Pharmacopoeia Convention of United States (HPUS) issued the first volume of its Homeopathic Pharmacopoeia Revision Service. Substances monographed in the HPUS are recognised as official drugs in current Food, Drug and Cosmetic Act and the Code of Federal Regulation. Homeopathic remedies are recognised as drugs by FDA. FDA has not subjected many of these remedies to pre-market screenings for safety and effectiveness as in normal or conventional drugs. In Homeopathy they use active natural substances such as plants, animals and minerals. Most of these materials are used to prepare Mother Tinctures by diluting in alcohol according to condition strictly defined in Homeopathic Pharmacopoeia of United States. Those who are licensed to practice Homeopathy in US vary according to state-by-state “scope of practice” guidelines, but they include M.D.s, D.O.s, dentists, naturopaths, chiropractors, veterinarians, acupuncturists, nurse practitioners and physician assistants. Three states have now specific licensing boards for Homeopathic physicians: Arizona, Connecticut and Nevada. Speciality certification diplomas for those prescribing homeopathic drugs are also granted through national boards of examination for M.D.s/D.O.s and N.D.s. Self help as well as professional training courses in Homeopathy are offered through the National Centre for Homeopathy (NCH) in Alexandria, Virginia. In the US, the Council on Homeopathic Certification is the new certifying body that conducts rigorous examination. The process involves evaluation of five case histories from a practitioner with six-month follow up before certification is achieved. Approximately 400 students graduate every year from the four naturopathic college and about 25% of these students choose Homeopathy as their speciality. As of 1998, CHC had certified almost 200 homeopaths granting them Certification in Classical Homeopathy.

In the US, homeopathic products initially were marketed exclusively through pharmacies, however the current market is mostly in natural and health-food stores.

In the US, a lot of stress is put on the standard and labelling requirements, for reasons of safety. The current Homeopathic Pharmacopoeia Convention of the United States has placed high priority on the safety of official homeopathic drug products in the market place. Official homeopathic drug products must be identified properly on the label by using HPUS. Potencies or degree of dilution are either indicated as numerals or the alphabets X, C or K. OTC homeopathic drug products have no side effects, but must carry all of the customary warning regarding pregnancy, nursing mothers and temper evident features. Homeopathic drugs are not subjected to carry any expiry dates but must meet all other requirements of FDA and CFR.

Children's remedies are the most successful segment of homeopathic drug market in the US. The main reasons for increase in interest in Homeopathy in the US is the recognition that :

- a. the disease of the immune system have increased (e.g. AIDS),
- b. the number of people suffering from incurable viral condition is increasing,
- c. bacterial infections are becoming resistant to commonly used antibiotics,
- d. allergies to food and other common substances are becoming more prevalent,
- e. chronic disability is affecting people more at younger ages.

An interesting feature to note here is that it is believed in the US, by many, that the future market will have both "high-tech" and "high-touch" component in the systems of medicine. This is likely to shift the focus, with significantly greater reliance on self care practice, wellness programs, therapeutics, nutritional and fitness regimens and greater emphasis on more fully integrated concepts of how a person's psychological state affects various physiological process. Homeopath is believed to fulfill these requirements.

European Union Homeopathic Market

Homeopathic medicines are uniquely recognised within European Union pharmaceutical legislation by two directives, which acknowledge the particular nature of homeopathic medicines and give them special status and requirement alongside rest of the conventional pharmacy.

In the EU, the main difference in requirement is that for single homeopathic medicines, for which no therapeutic claim is made, proof of efficacy is not required for them to be licensed and can be placed in the market.

Potentised medicines are prepared according to the instruction recorded in homeopathic pharmacopoeia. The two main pharmacopoeia used in Europe are the German and French Pharmacopoeia which differ in number of ways. There are over 3000 remedies listed in the German homeopathic materia medica. This list is continually being expanded as new medicines are 'proved' i.e. tested, for their therapeutic potential on groups of healthy humans.

The practice and study of Homeopathy is unregulated in most of European countries. The European Council for Classical Homeopathy (ECCH) represents the majority of professional homeopaths in Europe. They published "Guidelines for Homeopathic Education" in 1993. The European Committee for Homeopathy (ECH) represents the majority of doctors who practice unicist (German practice) Homeopathy. The ECH published a "European Programme of Basic Teaching Standards in Homeopathy" in 1992.

The European Council for Classical Homeopathy (ECCH) is an international council constituted of established association of professional classical homeopaths existing within individual countries in Europe. Their main aim is to maintain a register of trained and regulated homeopaths, set stringent educational and training standards and maintain code of ethics and practice. Overall, it has been observed that barring a few exceptions, Homeopathy and its practice is tolerated in all European countries. Only in a few countries law restricts professional homeopaths from practicing legally.

According to various sources, some interesting facts have surfaced. These pertain to the practice of homeopathy in some European countries.

France – 16% of population use homeopathic drug products on a regular basis, 90% of the pharmacies sell drug products. In France only medical doctors, veterinarians, dentists and midwives may treat patients and any of them can give homeopathic treatment and call themselves homeopaths. In France there are 18000 general practitioners 700 veterinarians and 2000 dentists prescribing homeopathic medicines. This does not, however, mean that they consider themselves homeopaths. Some give their patients homeopathic medicines only, but most of them do it to a variable degree.

England – 45% of conventional physicians refer to homeopathic practitioner and it is increasing at an annual rate of 39%. Homeopathy has been integrated within the national health care system in the United Kingdom for almost 50 years, and both expenses for consultations and medicines can be refunded when the patient has been treated in one of the homeopathic hospitals or when they have been referred to a homeopath by a medical doctor. Homeopaths offering such treatment can either be doctors who have specialised in Homeopathy or a professional homeopath who works in a doctor's practice. Expenses for consultations and medicines can be refunded in Germany, provided the practitioner is a medical doctor.

The British association for professional homeopaths, the Society of Homeopaths (SoH), has 2 500 members of which 1400 are practicing. The British association for homeopathic doctors has 1 000 members of which some 300 are practicing. One of the German associations for professional homeopaths, Homöopathie Forum (HF), also has over 1 000 members. In most countries there are no specific restrictions for homeopaths, but there are laws and regulations for anyone who treats patients. In addition there are restrictions for medical doctors and all other officially authorised health personnel.

In Germany only medical doctors and so-called "Heilpraktikers" are allowed to treat patient and prescribe homeopathic medicines.

In Norway they use the title “homeopat MNHL” (member of Norwegian Homeopathic associations “, in Denmark they are called Klassik homeopat MDSKH and in UK “RSHom”

In all the above countries homeopaths are organised. The Central Body of Registration has over 125000 registered homeopaths.

Australia - In Australia Homeopathy is not recognised officially but homeopaths are free to practice and patients are free to consult these doctors. In Australia, private insurance companies refund expenses. Approximately 1/4th of the health funds rebates a part of homeopathic treatment on condition that practitioner is a member of ATMS (an association of all complementary/ alternative therapies). Restricted medicines (allopathic and homeopathic) can be sold only after getting a certificate from Therapeutic Goods Act (TGA). TGA sets regulation on what therapeutic can be made about the product. The Therapeutic Goods Administration controls what can be sold in pharmacies and in what potencies. Other non-conventional medicines that are officially recognised are Chiropractors and Osteopaths.

In the following countries complementary and alternative therapies have been officially recognised.

Chiropractors - Norway, Sweden, Denmark, Finland, United Kingdom and Australia

Osteopaths - Finland, United Kingdom and Australia

Naturopaths - Sweden, Finland

Acupuncturist – Finland

Heilpraktikers - Germany

Bottlenecks and limitations

Bottlenecks and limitations that obstructs the development of homeopathic medicines are:

1. Lack of availability of raw materials: since this system originated in Germany some of the raw materials used are not found in India and they have to be imported. For example some of the plants that are not grown in the country. Homeopathic formulations are 95%

alcohol, but its poor availability and expensive nature leads many companies to use spirit or other cheaper substitute for alcohol. This reduces the quality of homeopathic drugs and loss of competitiveness in market.

2. Technical manpower: The homeopathic industry requires a lot of technical expertise, which is relatively deficient in availability.
3. Market: There is no organised trade body in homeopathic market, no pooling of market data and a general paucity of information, and large degree of undercutting. Trade discounts or discounts offered in homeopathic drugs are in the region of 50% whereas in conventional drugs they are at the most 25%. The industry is highly fragmented with many companies in the market competing for small segment. As a result the profit margins for many companies are extremely low.
4. Quality control and GMP: the GMP norm is not notified statutorily for quality control. The companies do not apply GMP norms strictly, whereas in some of the countries, where the system is recognised and practiced, they are very strict about GMP and quality control. Like in the US, the FDA regulations for GMP are mentioned.

Strategies and Proposed Solution

Homeopathy is considered to be useful for children and minor diseases. It can be used as first aid for common ailments if government of India decides to demarcate the incoming patients of minor ailment, skin problem and children problem for the treatment by Homeopathy. It can also save a lot of money spent on antibiotics and expensive chemotherapy agents. 3% of the medical expense is on Indian System of Medicine and 90% goes on allopathic treatment. These can be changed if there is change in policy of the government.

ISM&H education should be included in MBBS curriculum at primary level at least. This would help in introduction of Indian system of medicines in hospitals and the professionals employed for the treatment can suggest the Homeopathy treatment which would help in medical cost cutting.

GMP practices should be notified statutorily for Homeopathy like the way it has been notified for Ayurveda and Siddha and Unani systems of

medicines so that our industry become competent enough in the countries abroad where they are particular about the GMP standards such as US.

Since we have to import a lot of raw materials from other countries it is necessary for setting up of medicinal plant board. This has already been taken into action and passed by parliament when this report was being written. Some effort is being made of plant introduction by organisation like Bureau of plant genetics at Pusa.

Annexure 4 (i)
The Global Market

Not put up for Retail Sale

Put Up for Retail Sale

YEAR	TOTAL EXPORT (KG)	TOTAL IMPORT (KG)	TRADE BALANCE	TOTAL EXPORT (KG)	TOTAL IMPORT (KG)	TRADE BALANCE
1996-97	11628	110876	-99248	44690	8227	36463
1997-98	51998	102135	-50137	30515	17492	13023
1998-99	32565	171635	-139070	25603	60065	-34462

Source : Indian System of Medicine and Homeopathy 1998

Annexure 4 (ii)
Total Exports of Homeopathic Medicines (PRS+NPRS) of India

	1992-93	1994-95	1996-97	1997-98	1998-99
Countries	Exports Volume (Rs)	Exports Volume (Rs)	Exports Volume (Rs)	Exports Volume (Rs)	Exports Volume (Rs)
USA	29110	433218	3469365	5041640	1541725
Sri Lanka	16175	198245	1363473	728951	717484
Malaysia	452552	214640	177611	738572	851356
Russia		7511373	658787	13701516	315757
Spain	1670247		394000	175447	271069
Brazil			5350	1109094	
UK	164571	809644	407216	136663	1572313
Nigeria			1421080	814807	2627056

*Source : Indian System of Medicine and Homeopathy 1998
Annexure 2A*

Homeopathy Not Put Up For Retail Sale

YEAR	TOTAL EXPORT (KG)	TOTAL IMPORT (KG)	TRADE BALANCE
1996-97	11628	110876	- 99248
1997-98	51998	102135	- 50137
1998-99	32565	171635	- 139070

Source : Indian System of Medicine and Homeopathy 1998