CCRH Quarterly Bulletin
Vol. 24 (1&2) 2002

PRESENT SCENARIO OF HOMOEOPATHIC PHARMACEUTICAL INDUSTRY AND PROBLEMS FACED BY THEM

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Homoeopathic system is growing across the world, thanks to WHO's resolve to promote the alternative medicines in the developing countries, because of their low cost, low toxicity and higher acceptability. Use of Indian Systems of Medicine and Homoeopathy had surged by about 70% since 1989. This is now expected to grow 30% annually. The reasons for growth are:

(a) High cost of treatment of allopathic system of medicine.

(b) Serious side effects of allopathic medicines.

(c) Resistance to conventional therapy.

(d) Government and Confederation of Indian Industry working together to promote alternative systems of medicine.

(e) WHO's recognition of alternative systems of medicine.

(f) Research & scientific placement of these systems.

(g) C.C.H. (Education control and upgradation) by the Govt. of India.

(h) Inclusion in C.G.H.S., ESI, Railways and Public undertakings.

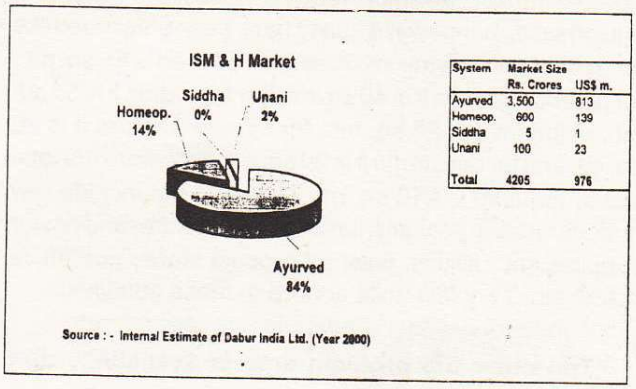
(i) Opening of Government owned Dispensaries and placement of one Government Doctor in each of the District Hospitals in major states.

(j) Drug Control, Quality awareness and Quality control by private and Government sectors.

(k) Technological updating of manufactory including multinationals entering the field.

The homoeopathic pharmaceutical industry may be anything between 250 crores (Economic Times, May 1996) with growth rate of 30% (Economic Times) to 600 crores (M/s. Dabur India Ltd. - 2000). There are about 800 units with far less than 1/10th having proper facilities for manufacturing homoeopathic medicines. There are certain ills which lower the growth rate:

INDIAN HOMOEOPATHIC INDUSTRY



System	Market Size Rs. Crores	US$ m.
Ayurved	3,500	813
Homeop.	600	139
Siddha	5	1
Unani	100	23
Total	4205	976

- Industry is largely dependent on the support of the trade to sell its items.

- The market is riddled with credit and liberal discounting systems.

- Small - level players are feeding the market with no control on quality.

- It is a very unorganized industry.

- Industry has no association or platform to voice their views.

- It does not have any interaction with research activities done by government or by schemes funded by the Government.

- It has to handle large number of Homoeopathic medicines, which may be upto 2000 in different potency levels.

Manager, Quality Assurance and Quality Control, Dr. Willmar Schwabe India Pvt. Ltd., A-36, Sector-60, Phase-III, Noida (U.P..), India

- Strict laws have been made to govern the industry like Schedule MI.

Schedule M1 enforces certain conditions for the manufacturing units as to its location and surroundings, building, quality of water supply, proper disposal of waste, health, clothing and sanitary requirement of staff, periodic medical check-up of the workers and the staff, washable working benches and walls, and container management. Apart from these, minimum requirements of the machines, equipments, manpower & space have been prescribed like for mother tincture minimum space required is 55 sq. mt., for potency section it is 40 sq. mt., for trituration it is 55 sq. mt., ointment it is 20 sq. mt., for syrups & tonics it is 20 sq. mt. and for eye drops it is 20 sq. mt. Therefore the total space required is 210 sq. mt. These do not include raw material stores, packing material stores, water and power supplies and utilities, finished product stores and office space etc. Very few units adhere to these conditions.

The other big problem area is availability and quality of raw materials.

Three major groups of Homoeopathic drugs are:

1. Drugs originated from chemicals and minerals.
2. Drugs originated from plants and animals.
3. Drugs originated from miscellaneous sources.

- Crude drugs in which constituents may vary from 0.1 to 99.5%.
- Mother tinctures - where the chemical components may vary from 0.001 to 3.0%.
- Dilutions, Triturations and Tablets - Medium level potencies 3x to 6x where the chemical constituents are in mg and ppm.
- Potencies like 7x, 8x 9x and 10x contain constituents in ppb range.
- Potencies above 10x contain substances in negligible quantity and cannot be analysed by chemical methods as per existing technology.

It is necessary to use the right species of the plants and animals for manufacturing of homoeopathic medicines. There are certain plant raw materials which are difficult to procure such as:

- *Berberis vulgaris*	*Berberis aquifolium*
Multilayer cortex(more than 5)	4-5 layers
Cork several layered and irregularly arranged.	Cork is single layered

- *Senega*

Spurious Senega (Mollugo oppositifolia)

Has vascular bundles in concentric ring and it contains much starch.

Not required, it should be examined carefully.

- *Rhus toxicondendron*

In T.S. each vascular bundle contains a secretory canal in phloem region while it is not present in other species of *Rhus tox*

- *Cantharis*

Lytta vesicatoria (Spanish fly)	Mylabaris (Chinese fly)
12-20 mm long 3-6 mm wide a shiny green	Black exoskeleton with usually 3 brightly orange coloured bands
Cantharidin 0.5-0.8%	Cantharidin > 1%

- *Blatta americana*	*Blatta orientalis*
Insect *B. americana*, wings cover whole of the body	While *B. orientalis*, the insect is small and its wings do not cover whole of the body.

The correct chemical raw material must be used but there is difficulty of procurement for some such as

- *Ferrum phos.* - HPI Vol. I, page 124.

Mixture of hydrated ferrous phosphate and ferric phosphate, and some hydrated oxide of iron. Grayish-blue amorphous powder.

Commercially available Ferric phosphate

Dihydrate white, grayish-white or light pink crystals or amorphous powder.

- *Calcarea carbonica, Causticum and Mercurius solubilis*

Should be made in strict accordance with Hahnemann's instructions.

- *Calcarea ova tosta* - HPI Vol. IV, page 34.

Contains several compounds of calcium i.e. Calcium carbonate, Calcium oxalate and Calcium lactate.

It is prepared from the shells of hen's eggs.

Total calcium - n.1.t 34%

The following should not be used

Calcum carbonate	-	Ca 40.04%
Calcium lactate	-	Ca 18-37%
Calcium oxalate	-	Ca 31.29%

- *Carbo vegetabilis*

  Should be prepared from birch or beach wood as per the method given in HPI Vol. I, page 94.

Proper emphasis is not given to Homoeopathic plants in short supply. The industry is suffering for want of good quality of raw materials.

Next big problem is market of medicines made from units with no control on raw materials or environment or methods for manufacture such as:

- Environmental control to exclude bacteria - HEPA filters and Laminar flow are essential.
- Contamination control from the appliances used - thorough cleaning with quality liquid cleaning agents and subsequent rinsing with distilled water, drying, flaming or steam treatment.
- Non-reactive vessels: recommended for neutral glass of high quality of stainless steel eg. SS 316 grade.
- Strict control over raw material used, following of proper manufacturing procedure given under General Instructions of Pharmacopoeia and absence of undesirable substances.
- Use of purest form of alcohol, lactose (sugar of milk), sugar, distilled water and other diluting media.

Next problem area is the quality of finished products, which may constitute of:

- It may consist of single constituents of a particular compound or number of compounds of different groups.
- Liquid and Tablet specialities
- Syrups
- Ointments
- Gels
- Toothpaste
- Hair oil
- Ear and eye drops, etc.

There is complete lack of quality control standards of finished products.

In the changed global scene where only internationally competitable quality can survive, we may have to think of

(a) Quality first
(b) User is king
(c) Avoid defects
(d) Long term vision
(e) Training for all
(f) Learning of facts
(g) Cost consciousness
(h) Team work
(i) Respect, humanity and consumer behaviour
(j) Operator in state of self control
(k) Proper leadership from top

Quality Linked Productivity

Quality
↓
Productivity
↓
Perfection
↓

Excellence

↓

Improvement

↓

Leadership

↓

Productivity is increased by emphasizing the positive control of quality.

Higher quality

↓

Enhanced Customer satisfaction

↓

Enhanced sales

↓

Increased Productivity

The Customer Wants:

- Right Quality

- Right Quantity

- At Right time

- At Right Cost

The industry can progress only with good quality products. Quality is never an accident; it is the result of intelligent efforts. There must be a will to produce superior things / services.

ILLS?

- The Government has prescribed the standards in Homoeopathic Pharamacopoeia, however, the implementation needs to be improved. In some of the monographs certain changes are required.

- The Government has prescribed the norms and laws in Drugs Act.

- The Government has the intention of introducing Good Manufacturing Practice (GMP), but the process should be expedited.

- The big question is whether all manufacturers follow the Government regulations.

Relaxed situation results in:

- Production without proper quality control of the raw material and the environment.
- Availability of different quality in the same product in the market depending on the manufacturer.
- In absence of testing methods for potentising preparations the physicians cannot make the difference between right and wrong.

What is required?

- The quality of the products from the Indian industry must be upgraded to international standards of GMP for the protection of the consumer.
- Existing laws and rules must be implemented.
- Manufacturers who do not comply should be asked to adhere to the rules for the protection of the consumer and to avoid giving Homoeopathy a "bad" name.

How to achieve these?

To achieve this, very strong controls or enforcement is required in the area of:

- Raw material control

- In process control

- Environmental control

- Requirement of qualified staff

This will result in growth of market and the Indian industry can ensure the proper quality of Homoeopathic medicines to the homoeopathic physicians of India and for export.