



NEW YEAR ISSUE



Pharma Web

Newsletter of
Tamilnadu Pharmaceutical
Sciences Welfare Trust



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Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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EDITORIAL

Dear Readers,

“I wish a happy and prosperous new year 2010 to all the readers”

This is the fifth issue for the quarterly period of October – December '09. This issue contains three articles namely “Regulatory aspects of Indigenous system of medicine under the Drugs and Cosmetics Act” by Mr. S. S. V. Krishnan, former Drugs Controller of Kerala. In this article the various systems of medicine - namely Ayurveda, Siddha and Unani have been explained on its regulatory aspects for getting manufacturing license from the Drugs Controller. The second article namely “Global Challenges for Pharmaceutical Industry” by Mr. Rashmi Ranjan Patra has clearly spelt the global scenario of pharmaceutical industries as on today and also job opportunities for the Pharmacy professionals. The third article namely “Make Pharmacy Your Career” by Mr. J. Jayaseelan, Secretary, IPA-Tamilnadu Branch narrated the Pharmaceutical industry profile in India and its expansion.

This article also gives information on various aspects of job opportunities for pharmaceutical professionals. This issue also contains the details of the scholarship award instituted by our Trust for the year 2009-2010 to the post-graduate students of Pharmacy. The Pharmacy Week celebration was conducted by various colleges in Tamilnadu. This time many colleges participated in this function. The celebration of the individual colleges is brought out in this issue with photos and the details of function. The 61st Indian Pharmaceutical Congress was held in Nirma University at Ahmedabad on 11th -13th December 2009. The conference was well attended by nearly 9,000 delegates. The Pharmaceutical Machinery Exhibition was one of the excellent one.

This issue also brought out various important Pharma news for the benefit of readers. I like to bring the important matter to all the readers about the Indian Pharmaceutical Association Convention to be held at Ramachandra University, Porur, Chennai on 13th and 14th March 2010. The IPA Tamilnadu Branch is organising this convention. We expect about 1500-2000 delegates to attend this convention. There will be a pre-convention program on 12th of March 2010. In this, pre-convention workshop on stability testing of medicines will be held in association with American Association of Pharmaceutical Scientists. This subject of stability study will be more useful to all the Pharmaceutical industry. There will be various workshops on community pharmacy, Pharmacy academics and regulatory and industry. I personally invite all the Pharmacy professionals and also Pharmacy students to take opportunity of this convention to enrich their knowledge.

It will be more interesting to know that our Trust has taken an initiative to create a database for the placement of fresh Pharmacy graduates. This information is highlighted in this issue. All the Pharmacy Professionals and the student community may utilize this opportunity for getting training or job opportunity in various field of Pharmacy.

With best regards,

R. Narayanaswamy

ARTICLES

REGULATORY ASPECTS OF 'Indigenous System of Medicine' UNDER THE DRUGS AND COSMETICS ACT

By Mr. S. S. V. Krishnan
Drugs Controller, Kerala (Red.)

This article is intended to provide information on the regulatory provisions applicable to manufacture of Ayurvedic, Siddha and Unani drugs under the Drugs & cosmetics Act 1940 and the Rules 1945. The administrative norms adopted by the regulatory agencies to implement these provisions may vary from State to State and from time to time. The effort made is to inform the class or classes of drugs regulated and the provisions thereof.

The Act: The definition of ASU drugs is the first norm to be looked into. Section 3 of Chapter I of the Drugs and Cosmetics Act defines as under:

“3. *Definitions.* In this Act, unless there is anything repugnant in the subject or context,--

(a) “Ayurvedic, Siddha or Unani drug” includes 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, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine, specified in the First Schedule;”

(h) “patent or proprietary medicine” means, --

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);”

The situations therefore are that there are basically two classes of ASU drugs namely those specified in the authoritative books of the respective systems of Ayurveda, Siddha and Unani as specified in the First Schedule of the Act and patent or proprietary medicines formulated with ingredients mentioned in the formulae described in those authoritative books.

The law as yet does not provide for manufacture of “New Ayurvedic, Siddha or Unani medicines.

The Act provides for constitution of a Drugs Technical Advisory Board for the ASU drugs and for appointing Inspectors and Government Analysts for the purposes of Chapter IV A pertaining to the ASU drugs.

As stated earlier, Chapter IV A is concerned totally with ASU drugs only, but we are limiting our discussions here to a few prohibitory clauses that are relevant to the matters under consideration

here. These include Section 33EEB and Section 33EEC. The provisions are as under:

“33EEB. Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs. No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.

33EEC. Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drug. From such date as the State Government may, by notification in the Official Gazette, specify in this behalf, no person, either by himself or by any other person on his behalf, shall

(a) manufacture for sale or for distribution--

- (i) any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drugs;
- (ii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and
- (iii) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, stock or exhibit or offer for sale or for distribution, any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder;

(c) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority;

Provided that nothing in this section apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients;

Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis.”

The points to be taken note of are namely (i) drugs are to comply with the standards prescribed (ii) manufacture of drugs for sale or distribution requires a licence under this Act and (iii) Vaidyas and hakims manufacturing drugs for use of their own patients do not require licence.

The Rules: As already stated, Part XVI of the Drugs and Cosmetics Rules 1945 pertains to the provisions applicable to manufacture of Ayurvedic drugs. The salient points of the provisions are:

I) Grant or renewal of licences:

- i) Separate licences are to be taken out in respect of each set of premises if manufacture is to be done in more than one set of premises (Rule 151).
- ii) Application for grant or renewal of licence is to be made in Form 24-D accompanied by a fee of Rs.1000/- (R.153).
- iii) Application can be made before the expiry or within one month of the expiry. If the application made after one month of expiry but within three months of expiry, the additional fee payable is Rs.600/- (R.153).

- iv) The fee for issue of Duplicate licence is Rs.300/- (R.153).
- v) Application for grant or renewal of loan licence is to be made in Form 24 E and the fee payable is Rs.600/- (R.153A).
- vi) The fee payable for renewal of loan licence one month after its expiry but within three months is Rs.300/- plus additional fee of Rs.300/-
- vii) Fee for issue of duplicate licence is Rs.150/-
- viii) Licence is granted in Form 25-D and loan licence in Form 25E.
- ix) The Certificates of renewals of the licence and loan licence are 26-D and 26-E respectively.
- x) The validity periods of these licenses are three years.
- xi) Conditions for grant or renewal of licence in Form 25-D:
 - A) Hygienic conditions as prescribed in Schedule T shall be complied with.
 - B) 'Good Manufacturing Practices as set out in Schedule T shall be complied with.
 - C) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least one person, who is a whole time employee and who possesses the following qualifications, namely
 - (a) A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of medicines recognized by the Central Government or a State Government for this purpose, or
 - (b) A diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government for this purpose, or
 - (c) A graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognized by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani systems of medicines, or
 - (d) A Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of Ayurvedic or Siddha or Unani drugs, or
 - (e) A qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicines, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognized by the Central Government.

The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualification in Siddha or Unani, as

as the case may be.

II) Conditions of licences:

158. *Conditions of licence* - A licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely

- (a) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw material and finished products.
- (b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw material as well as finished products, and to inspect the records maintained under these rules.
- I[(c) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.]

158-A *Conditions of loan licence*. A licence in Form 25-E shall be subject to the conditions stated therein and to the following conditions, namely

- (a) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.
- (b) The licensee shall comply with the provisions of the Act and of the Rules and with such further requirements if any, as may be specified in any Rules subsequently made under Chapter IV-A of the Act, provided that where such further, requirements are specified in the Rules; these would come into force four months after publication in the Official Gazette.
- (c) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other person on his behalf, of the raw materials and finished products.
- (d) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules have been observed.
- (e) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.

Rule 160. *Identification of raw materials* Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever test are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

Labelling requirements: These are prescribed in Part XVII, which reads as under:

PART XVIII LABELLING, PACKING AND LIMIT OF ALCOHOL IN AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

161. *Labelling, packing and limit of alcohol.* (1) There shall be considerably displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of the preparation together with quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and Adikarana, as are prescribed in the authoritative books specified in the First Schedule to the Act:

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with packing and reference be made to this effect on the label.

(2) The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E (1), be labelled conspicuously with the words 'Caution: To be taken under medical supervision' both in English and Hindi language.

(3) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani drug and on any other covering in which the container is packed namely--

- (i) The name of the drug. For this purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act.
- (ii) A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
- (iii) The name and address of the manufacturer.
- (iv) The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or 'Mfg. Lic. No.' or 'M.L.'.
- (v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot No." or "Lot" or any distinguishing prefix.
- (vi) The date of manufacture. For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.
- (vii) The words "Ayurvedic medicine" or "Siddha medicine" or "Unani medicine" as the case may be.
- (viii) The words "FOR EXTERNAL USE ONLY" if the medicine is for external application.
- (ix) Every drug intended for distribution to the medical profession, as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words "Physicians sample. Not to be sold" which shall be over-printed.
- x(a) Preparation (Asavas) with high content of alcohol as base

Name of the drug	Maximum size of packing
(i) Karpur Asava	15 ml
(ii) Ahiphensava	15 ml
(iii) Mrgamadasava	15 ml

(ix) (b) Preparations containing self-generated alcohol

Name of the drug	Maximum content of alcohol (Ethyl alcohol v/v)	Maximum size of packing
(i) Mritsanjivani Sura	16 per cent	30 ml.
(ii) Mahadrakshasava	16 per cent	120 ml.

(4) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper case or other covering used solely for the purpose of packing, transport or delivery.

161-A. *Exemption in labeling and packing, provisions for export of Ayurvedic (including Siddha) and Unani drugs.*- (1) Labels and packages or containers of Ayurvedic, Siddha and Unani drugs for export may be adapted to meet the specific requirements of the law of the country to which the said drug is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely :

- Name of the Ayurvedic, Siddha and Unani drug (Single or compound formulations;
- the name, address of the manufacturer and the number of licence under which the drug has been manufactured;
- batch or lot number;
- date of manufacture, along with the date for “Best for use before”;
- main ingredients, if required by the import country;
- FOR EXPORT;

Provided that where Ayurvedic, Siddha and Unani Single or compound drug not classified under First Schedule or Schedule E-(I), is required by the consignee to be not labeled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the Licensing Authority mentioned in Rule 152.

(2) the provisions of Rule 161 shall not apply to a medicine made up “ready for treatment”, whether after, or without, alteration, which is supplied on the prescription of a registered medical practitioner if the medicine is labeled with the following particulars, namely:-

- the name and address of the suppliers;
- the words “For External Use Only”, if the medicine is for external application.]

PART XIX

STANDARDS OF AYURVEDIC, SIDDHA AND UNANI DRUGS

168. *Standards to be complied with in manufacture for sale or for distribution of Ayurvedic, Siddha and Unani*

S. No.	Class of Drugs	Standards to be complied with
1.	Drugs included in Ayurvedic Pharmacopoeia.	The standards for identity, purity and strength as given in the editions of Ayurvedic Pharmacopoeia of India for the time being in force.
2.	Asavas and Arishtas	The upper limit of alcohol as self generated alcohol should not exceed 12% v/v excepting those that are otherwise notified by the Central government from time to time.]

169. Permitted excipients. Permitted excipients, i.e. additives, preservatives, antioxidants, colouring agents, flavouring agents, alternate sweeteners specified in the Table below are permitted in Ayurveda or Siddha or Unani drugs as per reference standard or grade under the Prevention of Food Adulteration Act (PFA), Indian pharmacopoeia (IP), British Pharmacopoeia (BP), United States national Formulary (USNF) and others as mentioned in the Table, namely:

TABLE

Permitted Excipients

Gum Acacia	PFA	Activated charcoal	IP
Activated charcoal	IP	Agar	PFA
Agar	PFA	Alginic Acid and its salts	PFA
Alginic Acid and its salts	PFA	Arachis Oil	PFA
Arachis Oil	PFA	Beeswax	IP
Beeswax	IP	Bentonite	IP
Bentonite	IP	Calcium Carbonate	PFA
Calcium Carbonate	PFA	Calcium Phosphate Dibasic	IP
Calcium Phosphate Dibasic	IP	Calcium Phosphate Tribasic	IP
Calcium Phosphate Tribasic	IP	Carbomer	IP
Carbomer	IP	CarnaubaWax	IP
CarnaubaWax	IP	Cellulose and its derivatives	IP
Cellulose and its derivatives	IP	Cetosteryl Alcohol	IP
Cetosteryl Alcohol	IP	Citric Acid and its salts	PFA
Citric Acid and its salts	PFA	Colloidal Silicon dioxide	IP
Gum Acacia	PFA	Carmellose sodium	IP

Dextrin and its Derivatives	PFA/IP
Dextrose	PFA
Emulsifying Anionic Wax	IP
Gelatin	IP
Glucose	PFA
Glycerin	IP
Guar Gum	PFA
Hard Paraffin	IP
Hydrogenated Vegetable Oil	PFA
Icing sugar	PFA
Invert Sugar Syrup	BP
Dextrin and its Derivatives	IP
Isopropyl Myristate	BP
Isopropyl Palmitate	BP
Kokam Butter	PFA
Lactose	PFA
Lecithin/ Soya Lecithin	USNF
Light Magnesium Carbonate	IP
Light Mineral Oil	IP
Liquid glucose	PFA
Liquid Paraffin	IP
Magnesium Aluminium Silicate	BP
Magnesium Carbonate	IP
Magnesium Oxide	IP
Malic Acid	PFA
Malt Extract	IP
Malto Dextrin	USNF
Mannitol	IP
Methacrylic acid Ethylacrylate	USNF
Microcrystalline Wax	IP
Peptic Enzyme	IP
Pectin	PFA
Poloxamer	USNF
Polyethylene Glycol	IP
Polymethacrylate	USNF
Polysorbates	IP

Polyvinyl Alcohol	IP
Polyvinyl Pyrrolidone	IP
Polyvinyl Acetyl phthalate	IP
Potassium Bicarbonate	IP
Povidone and its derivatives	IP
Propylene Glycol	IP
Shellac	IP
Skimmed Milk Powder	PFA
Sodium Bicarbonate	IP
Sodium Chloride	PFA
Sodium Edetate	PFA
Sodium Hydroxide	IP
Sodium Lauryl sulphate	IP
Sodium Silicate	IP
Sodium Starch Glycollate	IP
Sodium Stearyl Fumerate	IP
Soft Paraffin	IP
Sorbitan Esters	BP
Sodium Lauryl sulphate	IP
Sorbitol	IP
Starch and its derivatives	IP
Stearic Acid and its salts	IP
Sucrose	IP
Talc	IP
Tartaric Acid and its salts	IP
Titanium Dioxide	IP
Tragacanth Gum	IP
Wax non-ionic emulsifying	IP
Wax Microfine	IP
White Petroleum Jelly	IP
Xanthan Gum	USNF
Xylitol	USNF
Yeast	PFA
Yellow Petroleum Wax	IP
Yellow Petroleum Jelly	IP
Zinc Oxide	IP

Preservatives

Acetic Acid	PFA
Benzalkonium chloride	IP
Benzathonium chloride	IP
Benzoic Acid and its salts	PFA
Bronopol	BP
Butyl Paraben	BP
Cetrimide	BP

Ethyl Paraben	BP
Imid Urea	In-house specification
Propyl Paraben and its salts	PFA
Methyl Paraben and its salts	PFA
Phenyl Mercuric Nitrate	IP
Propionic acid and its salts	PFA
Sorbic acid and its salts	PFA

Antioxidants

Ascorbic Acid and its salts and esters	PFA
Butylated Hydroxyl Anisole	PFA
Butylated Hydroxyl Toluene	PFA

Gallic Acid esters	PFA
Potassium Metabisulphite	PFA
Sodium Metabisulphite	PFA

Colouring Agents	As permitted under Rule 127 of the Drugs and Cosmetics Rules, 1945
Flavouring Agents	As permitted under Fruits Product Order and PFA Act, Rule 63.
Alternate Sweeteners	As permitted under Fruits Product Order

Note:

1. Preservatives, alternative sweeteners and colouring agents shall be mentioned on the label for information of the user.
2. Additives used in various processes and to formulate dosage form shall be mentioned clearly with quantity in the flow sheet and the record shall be maintained by the manufacturing unit.
3. Manufacturers shall be responsible to ensure rationality, safety and quantity of various additives used in the formulation. This will be as per IP/ BP/ USP/ PFA/ or other standard reference book.
4. The provisions of the Schedule T will be detailed separately in the next part of this presentation.





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GLOBAL CHALLENGES FOR PHARMACEUTICAL INDUSTRY

By. Mr. Rashmi Ranjan Patra

Vice President (Operations), M/s Actavis Manufacturing Pvt. Ltd., Chennai

Pharmaceutical industry is one of the most important sector to provide proper healthcare system in any country. Among various industrial sectors, Pharmaceutical Industry is an evergreen sector. In order to establish, grow and survive at global level, we have to face and overcome various challenges at global perspective.

Following areas are focused in this article to describe in brief about “Global challenges for pharmaceutical industry”.

- Global Pharmaceutical Industry and Global pharmaceutical sales
- Pharmaceutical Scenario India
- SWOT Analysis of Indian Pharmaceutical Market
 - ✓ Strength/advantages of India
 - ✓ Weakness/challenges for India
 - ✓ Opportunities for India
- Opportunities for Pharmacist in industry
- Conclusion

Global Pharmaceutical Industry and Global Pharmaceutical Sales:

In order to face the challenges, it is mandatory to know about the industry status, namely the phase of life cycle of market, market size in terms of volume, sales output (profit), growth at global level etc., which provides an idea of structuring out the plan for overcoming the challenges ahead.

The global Pharmaceutical Industry market is estimated to be about US\$773.1 billion. The market value is expected to grow between 3.0% to 6.0% by 2013.

The pharmaceutical sector is a regulated market in almost all the regions of the world and 90% of the revenue of the growth is from regulated market only.

On the global view, North America is the single largest market which accounts for approximately 40% of global sales (US \$ 309.24 billion); the rest of 60% is shared among other regions of the world. The other regions of the world i.e. Latin America, Asia, Africa, Australia and Europe are the fastest growing markets, at the rate of Compound Annual Growth Rate (CAGR) of 11.0 -14.0% (As per IMS Health market Prognosis, March 2009) (Ref Figure 1 and Table 1). (Refer “Table 2” for the statistics of sales turnover and % growth over a period of time - 2001 to 2008)

Figure - 1
Total Un-audited and audited global pharmaceutical market by region

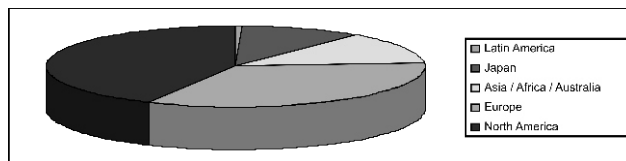
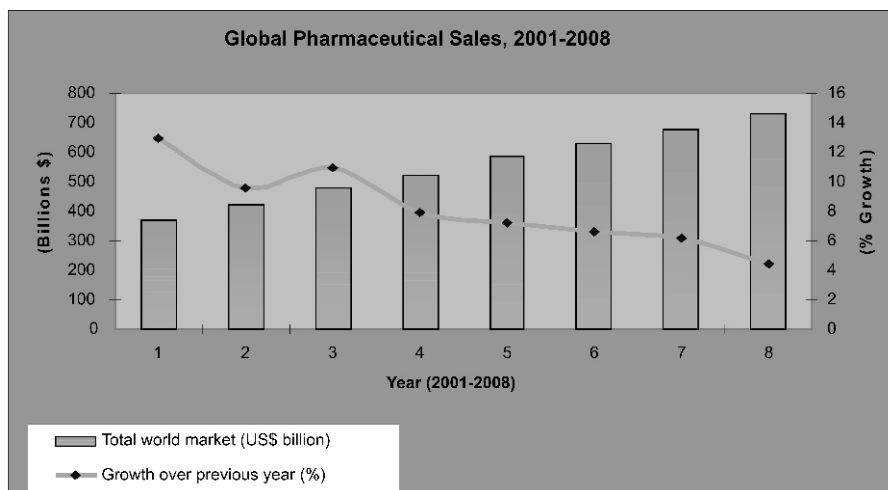


Table 1
% Growth Const. US\$

Region	2007 %Growth Const. US\$	2008 %Growth Const. US\$	2003-2008 CAGR% Const. US\$	2009 Forecast % Growth	2008-2013 CAGR % Const. US\$
North America	4.4%	1.4%	5.7%	-1 - 0%	-1 - 2%
Europe	7.1%	5.8%	6.4%	3 - 4%	3 - 6%
Asia / Africa / Australia	15.0%	15.3%	13.7%	11 - 12%	11 - 14%
Japan	4.2%	2.1%	2.7%	4 - 5%	1 - 4%
Latin America	12.8%	12.6%	12.7%	9 - 10%	11 - 14%

Table 2



Pharmaceutical Scenario India

From the global perspective, it is very explicit from above that pharmaceutical industry is one of the biggest revenue yielding market, which grows between 11 to 14 % in other regions apart from North America.

India, with its capabilities of having skilled scientists, strong chemistry skills, regulatory capabilities and quality manufacturing, has positioned in favourable place to capitalize in the global pharmaceutical opportunities. India also maintains its position in pharmaceutical sector as 4th largest pharmaceutical producer and with 8.0% share of global production by volume and 13th position in terms of value.

According to ORG IMS, Indian pharmaceutical market grown about 18.3% in June and 8.9% in July 2009. As per KPMG C II study, it is expected that between 2007 - 2011, Indian pharmaceutical market will grow above 16.0%.

The above study results are the growth rate of pharmaceutical industry at National level. At the international level, Indian Pharmaceutical Market (IPM) is expected to grow in double digit whereas other regions like US and Europe are stagnating. As per FICCI with E&Y, IPM growth (in sales) will be triple to US \$ 20 billion from US \$ 7.1 by 2015 with (CAGR) of 12.3%.

The above said growth phase is applicable to not only with respect to pharmaceutical production but also to other services like clinical trials and data management. The scope for R&D is clearly observed from the investment of leading pharmaceutical industries in R&D. (For complete details refer the below “Table 3).

Table 3

Investment by top 20 Indian pharmaceutical companies			
[Rs. crore]			
Company Name	R&D expenses	Sales	R&D as % sales
Ranbaxy Laboratories Ltd.	460.5	3,656.2	12.6
Dr. Reddy's Laboratories Ltd.	292.8	4,146.2	7.1
Sun Pharmaceutical Inds. Ltd.	188.3	1,722.1	10.9
Cipla Ltd.	175.7	3,658.0	4.8
Cadila Healthcare Ltd.	161.8	1,758.5	9.2
Lupin Ltd.	142.1	2,051.7	6.9
Wockhardt Ltd.	126.7	1,189.0	10.7
Torrent Pharmaceuticals Ltd.	112.1	895.2	12.5
Panacea Biotech Ltd.	107.2	843.0	12.7
Aurobindo Pharma Ltd.	96.7	1,991.0	4.9
Matrix Laboratories Ltd.	92.1	775.7	11.9
Orchid Chemicals & Pharmaceuticals Ltd.	63.0	934.2	6.7
USV Ltd.	59.6	659.2	9.0
Ind-Swift Laboratories Ltd.	58.5	356.1	16.4
Biocon Ltd.	47.9	887.2	5.4
Glenmark Pharmaceuticals Ltd.	43.3	838.8	5.2
Strides Arcolab Ltd.	37.5	395.2	9.5
Dabur Pharma Ltd.	35.7	322.0	11.1
Piramal Healthcare Ltd.	35.3	2,001.3	1.8
Alembic Ltd.	34.5	722.6	4.8

SWOT analysis of Indian Pharmaceutical Market

According to management theory, before stepping into any planning activity, to achieve a target, each one should undergo SWOT analysis (Strength, Weakness, Opportunity and Threat) and to plan, execute and achieve the target/goal.

In global level the pharmaceutical market is in the growing phase of its life cycle. Thus, in order to achieve our aim of being part of growth and revenue, the SWOT analysis is carried out and the output is as follows:

Strength/Advantages of India

1. India is strong in Information technology, pharmaceutical technology, biotechnology and synthetic chemistry, which are the fast growing fields in the global wide
2. World's 2nd largest population of scientists, pharmacists, engineers
3. Low labour cost
4. Low infrastructure cost
5. Producer of drugs at lowest price but of course not least in Quality
6. Abundant talents with managerial and technical skills
7. Large number of facilities approved by WHO, GMP, UK MHRA, Health Canada, TGA Australia, MCC South Africa, etc.
8. Ideal for conducting clinical trials due to genetic diversity (5/6 genetic diversity is available in India)
9. Availability of cost effective quality of APIs
10. More number of English speaking population
11. Globalisation policy of Government
12. Collaboration between academy and industry
13. Setup of biotech park and knowledge park to attract industries
14. Entry into generic market
15. Highest number of USFDA approved facilities outside USA
16. Highest number of DMFs and ANDAs filed outside USA
17. Accounts for 1/3rd DMFs in USA and 29% of all approved ANDAs in the USA are from India, ranking the country number 2 next only to USA
18. India ranks next to USA with a share of 21% of patent challenges
19. Educational institutions offering courses on IPR, RA, QC and CRs
20. Indian companies are becoming true MNCs by acquiring facilities overseas.
21. Finally, India is emerging leader in Pharmaceutical Industry

Weakness/Challenges for India

1. Global regulatory compliance
2. New IPR regime
3. Increased regulatory scrutiny
4. Generic completion
5. Shortage of trained man power
6. Retaining technical manpower
7. Limited skill in addressing global issue
8. Lack of supporting infrastructure
9. Government decisions
10. Emphasis on Research and Development
11. Cost of new molecule development
12. Compliance with international regulatory guidelines
13. Collaborations with effective partners for R&D
14. Government, academia and industrial matrix
15. Strong knowledge of Intellectual property
16. Merger & Acquisition and consolidation
17. 24x7 Regulatory compliance

Opportunities

1. Patent expiry between 2009-2013, is drugs worth around 90 -120 billion, thus opportunity for generic products is
2009 - 19 billion
2010 - 12 billion
2011 - 32 billion
2012 - 24 billion
2. Out licensing of APIs and Formulations
3. CRAM (Contract Research and Manufacturing)
4. Clinical Research

Opportunities for Pharmacists in Industry

After successful completion of B. Pharmacy, the candidates have scope in the following departments of Industry:

- ▶ Production
- ▶ Quality Control/Quality Assurance
- ▶ Medical Representative in Sales
- ▶ Product Executive in Marketing
- ▶ Business Development
- ▶ Materials Management

After successful completion of M. Pharmacy, the candidates have scope in the following departments of Industry:

- ▶ Formulation Development
- ▶ Analytical Development
- ▶ Quality Assurance/Quality Control
- ▶ Regulatory Affairs
- ▶ Intellectual Property Rights
- ▶ Clinical Research
- ▶ Bio analytical
- ▶ Technology Transfer

If the Strength and Weakness are scrutinized, it is observed that collaboration of Industry, Academics and Government is placed as both strength and weakness, why so?

Industry provides knowledge and tools with which to convert these findings to practical applications.

Before looking in depth of the differences in the platform of Industries and academics, it should be accepted by everyone that, the common goal of both industries and academics is to *“improve the patient health”*.

The Finished product of academics (students) is the raw material for the industry and the industry needs the material which can be used as such.

Expectation of Industry from the students

1. Technical knowledge of subject
2. Awareness on patents
3. Computer skills
4. Willingness to learn
5. Ability to work in team
6. Initiative
7. Ethics and integrity
8. Leadership
9. Proficiency in English language
10. Communication skills
11. Analytical ability
12. Discipline
13. Creativity

The requirements of industry can be met if the weakness is converted into complete strength by carrying the following:

1. Pharmacy courses to be realigned with the job requirement
2. Courses should include exposure to guidelines issued by ICH, GMP, GLP, GCP etc.
3. Courses should include exposure to documentation requirement for regulatory submissions in different markets
4. Colleges should provide different lab model process equipment and analytical instruments and train the students about the operations
5. Access to journals, Pharma magazines and various regulatory websites
6. Mandatory industrial project work for graduates
7. Emphasis on quality assurance (QA), regulatory affairs (RA) and intellectual property rights (IPR) during post-graduation
8. Exposure of students to various national and international conferences / seminars /symposia/exhibitions
9. Industrial training as part of syllabus to obtain the degree
10. Exposure to international regulatory guidelines issued by ICH, USFDA, MHRA, WHO GMP, TGA, MCC, Schedule M etc.
11. Pharmacy colleges to encourage and assist the faculty members for updating their knowledge on latest developments
12. Collaborations between industry and academics
 - Development
 - Clinical development by Academics and Clinical trials by Industries
 - Preformulation studies by Academics and Pharmaceutical Development by Industries
 - Galenical innovations by Academics and Stability studies by Industries
 - Regulatory Affairs (new regulations)
 - Project management
 - Manufacturing (new technology, tools, machineries and process)
 - Quality Assurance
 - Packaging (new materials and techniques)

13. The various collaborative models are
- ▶ Joint Research
 - ✓ Conducted jointly by the faculty and students of University and representatives from Industry
 - ✓ Conducted partly at University campus and partly at the Industrial site
 - ✓ Progress monitored jointly by Senior representatives from both sides
 - ▶ Summer Interns
 - ✓ University students work on an industrial project at industrial site for the summer
 - ▶ Government-University-Industrial Consortium
 - ✓ Industrial Partners and university faculty select specific projects to pursue
 - ✓ Support is from the Government

The above said collaboration can be achieved if the government plays vital role in promoting collaboration, enhance funding of research to academia as well as industry and create an environment where industry and academia would work together.

The above said collaboration is successful only if the following are achieved:

- ▶ Overlapping or complementary expertise
- ▶ Mutual trust
- ▶ Clearly defined research goals and expectations
- ▶ Common focus on deliverables
- ▶ Seamless communication between participants
- ▶ Acceptable intellectual property agreements
- ▶ Existence of a pool of individuals with established skills and experimental capabilities
- ▶ Networking and geographical proximity

Conclusion

In nutshell, the opportunity for Indian pharmaceutical industry at global level is very good, strength of Indian pharmaceutical industry is more compared to weakness/threats and the weakness can be converted into strength by having proper vision and feedback but not as an single individual or an single company or an university or by government but as a collaboration of all from the industries, academics and government agencies.

*“Look at the sky
We are not alone.
The whole universe is friendly to us and
Conspires only to give the best to those
Who dream and work”*

Dr. A. P. J. Abdul Kalam



MAKE PHARMACY YOUR CAREER

Lecture by Mr. J. Jayaseelan, Director, M/s Novel Therapeutics Pvt. Ltd. And M/s. Delvin Formulations Pvt. Ltd., Chennai during the Valedictory function of National Pharmacy Week Celebration by IPA, TN Branch on 5th December 2009.

48th
National Pharmacy Week Celebration



Theme:
Make Pharmacy Your Career

J. Jayaseelan
Director,
Novel Therapeutics Pvt. Ltd. & Delvin Formulations

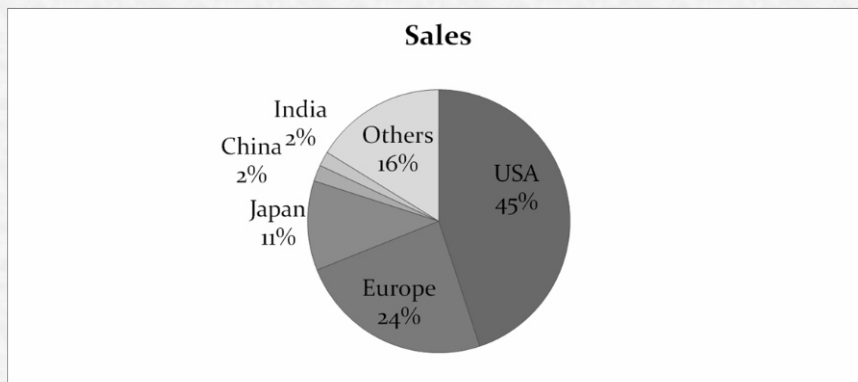
Hony Secretary – Indian Pharmaceutical Association (TN Branch)

Objective

Help younger generation to understand the scope of pharmacy career and making the future talents to enter this profession

Can India be a Pharmaceutical Superpower in 2020

Global Pharmaceutical Market - USD 735 bn



Exciting Times in Indian Pharmaceutical Industry

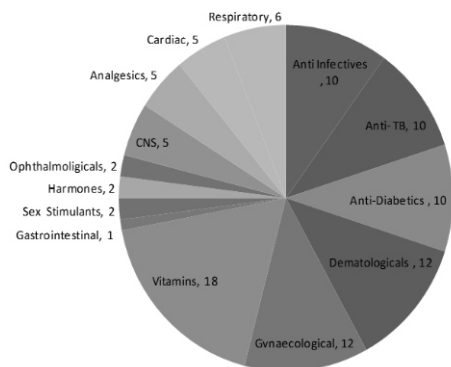
- India is having largest USFDA approved facilities outside USA.
- India is the 4th largest manufacturer of Pharmaceuticals in the global market.
- In value, India is 14th globally, which clearly shows that the prices of the medicines in India are lowest in the world.
- Out of USD 13 bn total Indian Pharmaceutical Industry the export generated is 5.8 bn and domestic sales is 7.2bn
- Out of 10 Top Pharmaceutical companies in India more than 50% of their annual turnover comes from exports.

The Indian Pharma Advantage

- Highly skilled and motivated scientists
- Proven expertise in process chemistry and pharmaceutical sciences
- Growing experience with US FDA / and other international regulatory compliances
- High quality manufacturing facilities with significant capacity upside
- Speed – Recruitment of patients & conducting clinical trials
- Cost of conducting clinical trials in India ~40 – 60% of developed markets
- India has strong IT skills for Clinical data Management

Domestic Growth Drivers

Shift in Disease pattern – Few years back, it was dominated by antibiotics & antibacterial. But now



Indian domestic market is steady and growing 14 to 15%

GROWTH Drivers for INDIAN Exports

CRAMS : Contract Research and Manufacturing Services – This turns out to be the biggest opportunity for Indian Industry.

Weaker pipelines & Rising approval times : The blockbuster drugs worth US\$ 47 billion are getting off patent in next 4 years.

Contract Manufacturing : Manpower costs in India are 70% lower than USA. Setting up FDA approved plants is 30% cheaper in India. Global companies have started outsourcing the manufacture of intermediates, API & generic drugs from countries like India & China.

Indian Crams Players

Company	No of plants	Approvals	Since	Client Base
Dishman	5	US FDA	1999	Solvay, Merck, Astra Zeneca , GSK, KRKA
Jubilant Organosys	8	US FDA, COS, TGA	1992	Syngents ,15 of the top 20 global pharma companies
Primal Healthcare	8	US, FDA, UK MHRA, Korean FDA, MCC SA	2003	Pfizer, AMO, boost , Wyeth
DRL	2	US FDA	2001	Over 5 big pharma & over 25 emerging pharma companies
Divi's Lab	3	US FDA, MEB Italy, TGA, ALFA Italy , DGMP Belgium , Health Canada, PMDA Japan	1990	Relationship with 20 of the 25 top players in the global market
Shasun pharma	5	US FDA, UK MHRA , UKMCA, TDP Canada, EDQM	2006	Technology licensing to Merck&Co, US & H Lunbeck , The Netherlands
SuvenLife sciences	3	US FDA	1994	Eli Lilly preclinical CNS molecule
Candila Health care	2	US FDA	2004	Nycornd , Hospira , Madeus
Hikal	1	US FDA	2001	Pfizer , Alparma

Threat on Big Pharmaceutical Companies

- Drugs worth around USD 47 billion are getting off – patent in the next three years
- Declining Exclusivity : The possibility of recovering huge investment made in research is becoming more & more remote because of competition.
- There is increased penetration of generics in markets where innovators have traditionally been strong.
- There is drastic reduction in drug approvals from USFDA. In 2007 there were only 19 approvals; the lowest in last 24 years.

COST Cut Down Initiatives Planned by Big Pharma

Company	Strategy Rationale
Pfizer	• Reduce Cost by USD 2billion by closing 5 research facilities ,closing /selling 3 manufacturing facilities &reduce 10% of workforce (10,000 people) • Outsource as much as 30% of manufacturing (currently it outsources 15%)to facilities in Asia ,mainly India &china
Astra Zeneca	• Reduce cost by USD 900 million by 2010 by reducing 11% of Global workforce (over 7000 jobs), stopping production in most of its 23 manufacturing sites &starts outsourcing to china, India &East Europe. • Close its in house production of Alps for conventional drugs &start outsourcing more advanced manufacturing &logistic operations.
Glaxo Smithline	• Reduce cost by USD 1.5 billion through a restructuring program targeting sales &manufacturing • Has already closed 28 plants since 2000 • 80 plants currently operating to be reduce further by 2010 • Outsourcing the manufacturing of off –patent products &outsourced drug candidates to eventually out number in –house discovered drugs.
Bristol – Meyers Squibb	• Reduce spending by over USD 1.5 billion over next 3 years, by reducing general &administrative operations by simplifying, standardizing, &outsourcing processes &services. • Reduce the number of its brands mature products portfolio by 60%over the next 4 year &also reduce more than half the number of manufacturing facilities by 2010 • A net 10% reduction in workforce over the next 3 years
Novartis	• Cut Spending by USD 1.6 billion by 2010. • Reduction of approximately 2500 jobs (about 2.5% of the group's current global workforce).

NCE /DDD very expensive - Scaling up through collaborative efforts – prominent collaborative deals in NCE Research

Indian company	Molecule	Indication	Nature of Deal	Global partner	Deal Amount
Glenmark	GRC 3886	Asthma COPD	Out –licensing	Forest	USD 190 Million
	GRC 6211	Asthma COPD	Out –licensing	Tejin	Upfront & milestone payments upto USD 53 million
DRL	DRF1042	Cancer	Joint development	Clintect	Not disclosed
	DRF2593	Type II Diabetes	Joint development	7TM pharma	Not disclosed
	Drugs targeting 7TM receptors	Metabolic disorders	In licensing	Eli Lilly	NA
Primal healthcare	Preclinical candidates	Metabolic disorders	In –licensing	Eli Lilly	USD 100 million payments royalties on future global net sales
	Selective target in onco	Oncology	In –licensing	Merck co	Upto USD 175 million per target +royalties on sales
Alembic	NDDS for keppra@ XR	Anti-epileptic	Out –licensing	UCB, Belgium	USD 11 Million milestone payments+ royalties on future global net sales
Suven	Preclinical candidate		Joint	Eli Lilly	USD 11 Million milestone payments+ royalties on future global net sales

Few Examples of Acquisition by Indian Companies

Date	Target Name	Target country	Acquirer Name	Deal value	Rationale
Oct-06	Pinewood Laboratories	Ireland	Wockhardt Ltd	150	Entry into Ireland and to consolidate its position in UK and Germany leverage on pinewood marketing network and other a wider basket of products
Oct-06	Cantabria pharma SL	Spain	Wanbury Ltd	62.6	Entry into the European generics market
Dec-06	Be –tabs pharmaceuticals	South Africa	Ranbaxy Laboratories Ltd	70	Strengthened Ranbaxy south Africa operations Be –tabs in south Africa largest penicillin manufacture and the fifth largest generics player
Dec-06	Genemedix	U.K	Reliance Life Sciences	63.2	Access to Genemedix manufacture and clinical research facilities to launch a bio-similars portfolio in European markets
Dec-06	Pharmacin International	Netherland	Aurobindo pharma ltd	NA	Access to several key European markets and widen products portfolio
Jan 07	Biosciences co ltd	Thailand	Dabur pharma ltd	NA	Access to the marketing and distribution network for Thailand rapidly growing ecology market
Mar07	Medicaments As	Czech republic	Glenmark pharma ltd	NA	Entry into the Czech Republic and Slovakia market
Apr-07	Nippon Universal pharmaceuticals	Japan	Cadia Healthcare Ltd	NA	Leverage on Nippon manufacturing base and strong distribution network to gain access to 4,000 hospital and clinic
Apr- 07	Negma Lerads sas	France	Wockhar Ltd	265	Entry into the French market and access to Negma portfolio of 172 patents and distribution network
May-07	Disapa S P A fermentation facility	Italy	Strides Arcolab	NA	Access to a U.S FDA and EU approved facility with strong technology and fermentation skills
May 07	Quimica pharma Nikko do brasil ltd	Brazil	Cadila healthcare ltd	NA	Entry into brazil a branded generics space

Issues and Challenges

Sustaining Export : The intangible benefits can be exposure to global standards, manufacturer of high quality goods .

IPR issues : New patent law integrates India into the global pharma market.

R & D Focus : Indian companies are not used to this long term approach as sometimes it may take years to get a good lead. Average R&D spend of Indian companies is growing at a rate of 18% annually.

Cautions

Impact of Global Economic Meltdown : The global economic meltdown will have its impact on India. The Pharmaceutical Industry is known to be recession-proof.

USFDA Incidents : Untoward incident with regulatory agency of other countries raises doubts about quality in the mind of the global consumer.

Shortage of trained manpower : Although India claims to have the largest pool of manpower, TRAINED manpower is a concern.

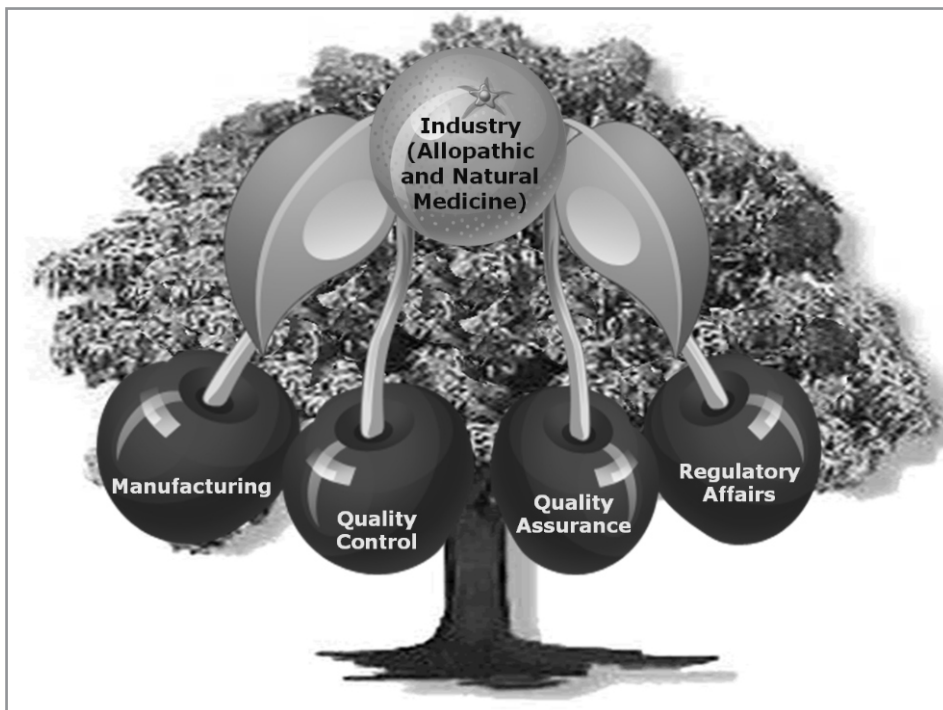
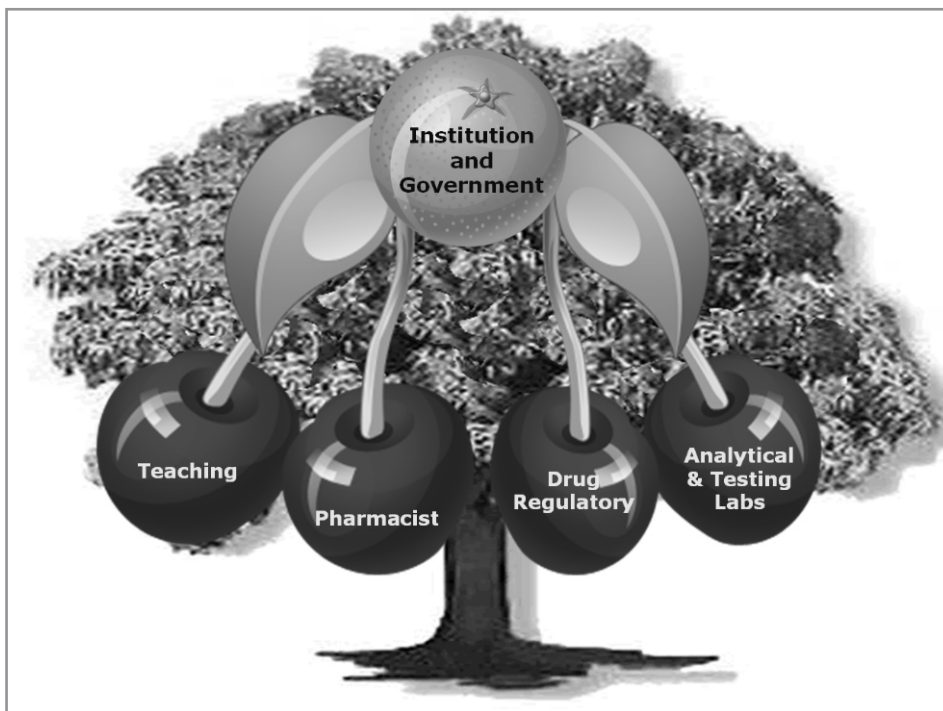
Chinese aggression : We have to guard against our ambitious neighbors who are meticulous in their approach, very hard working .

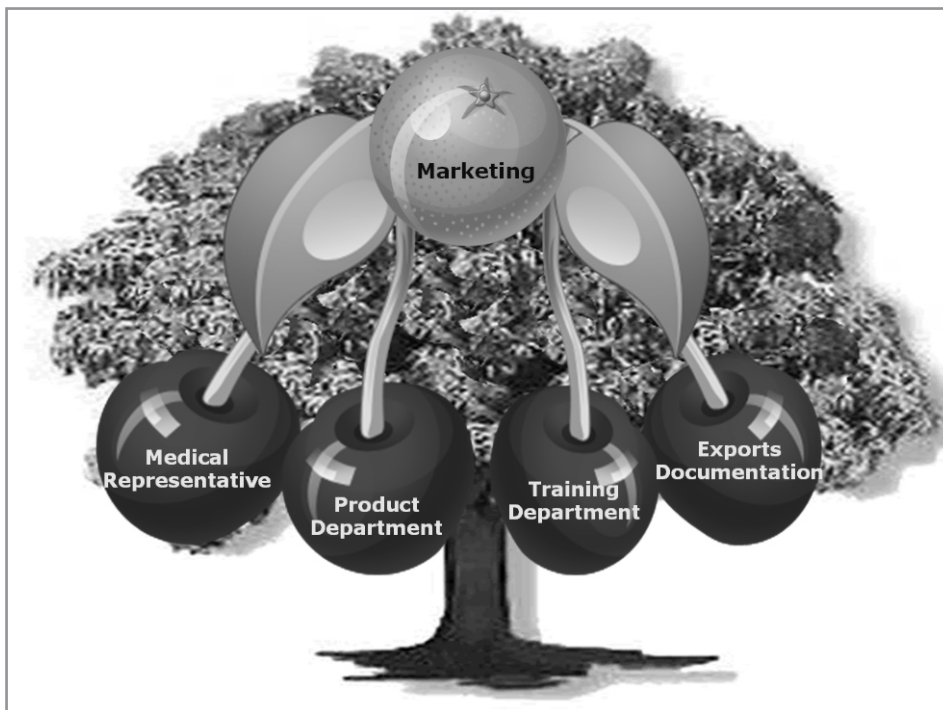
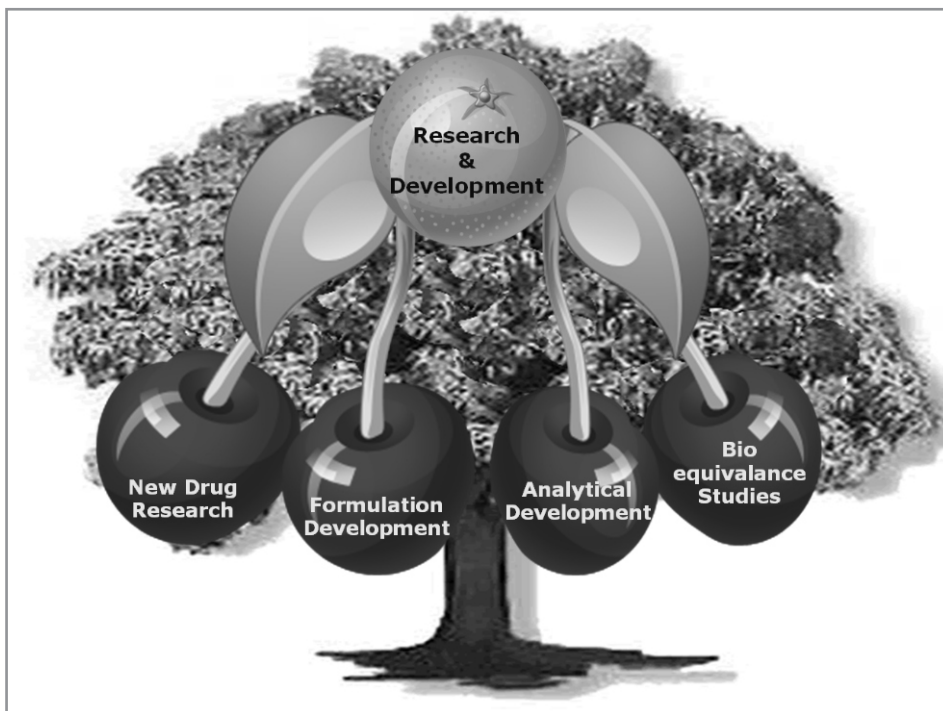
Making of Super Power

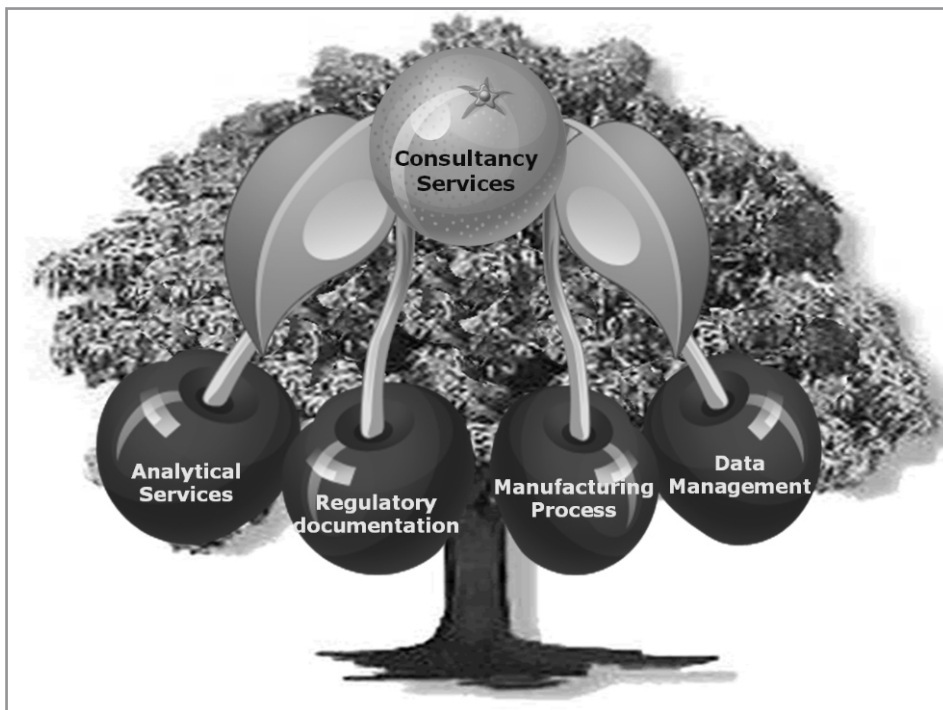
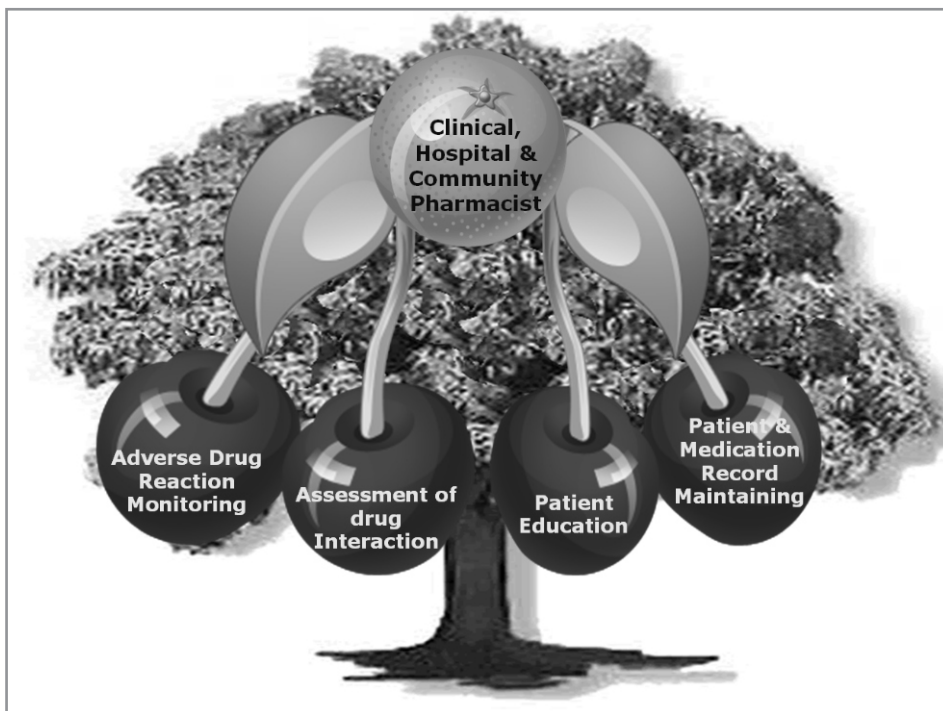
- Respect for IPR regime
- Forecast to reach \$60 bn by 2020
- Trained, skillful manpower
- Good understanding of regulations
- Good growth in domestic market
- Performance in the regulated markets
- Acquisitions in Europe and USA to gain market share
- Reverse brain drain
- Focus on DDD – long term goal
- Manufacturing shift to Asia
- Contract research

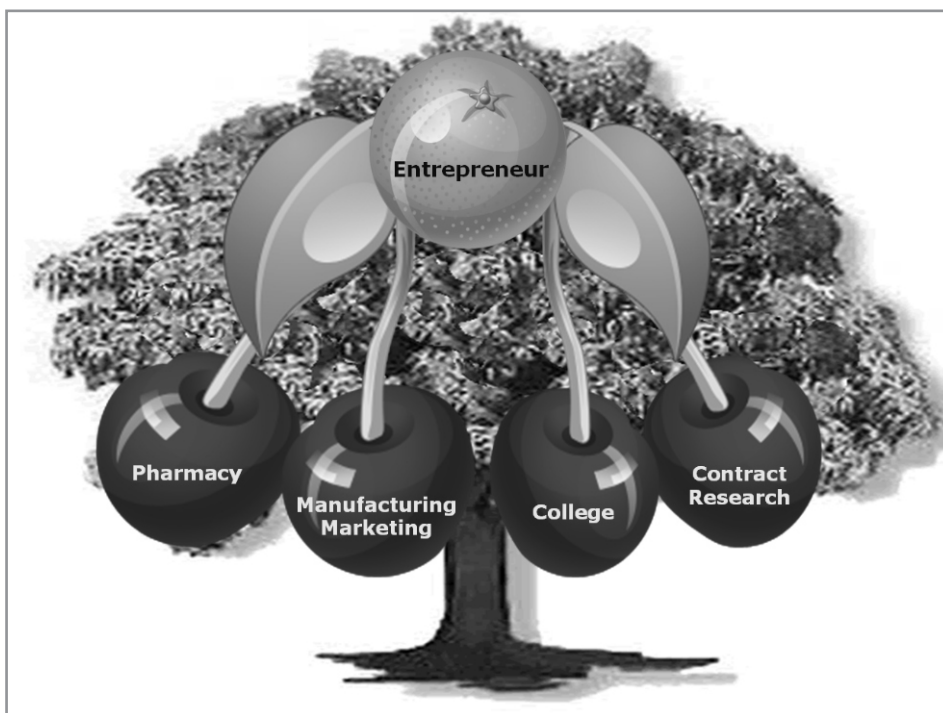
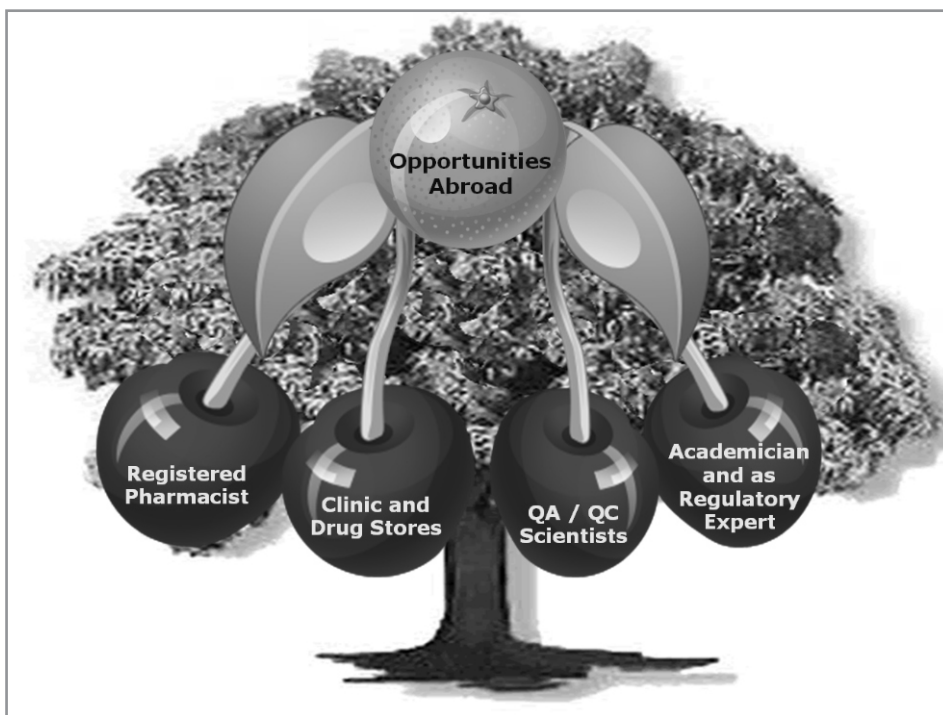
Making India one of the top 5 players in the world











M. PHARM SCHOLARSHIP AWARDED BY THE TNPSWT

FOR THE YEAR 2009 - 10

Every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awards scholarships to selected M. Pharm final year students from various colleges in Tamilnadu for their on-going project work.

This was the 12th year of these awards. This year, we received 252 applications from seven different branches of Pharmacy from 19 Colleges. 242 synopses were sent to Dr. Sasmal, Professor & Head Dept. of Pharmaceutical Sciences, Birla Institute of Technology, Ranchi and his team for evaluation. Based on their best marks, **21 students** have been selected for award for scholarship as per the following details:

First Rank	---	Rs. 8,000/- each for 7 candidates.
Second Rank	---	Rs. 7,000/- each for 7 candidates
Third Rank	---	Rs. 6,000/- each for 7 candidates

SUBJECT-WISE BREAK-UP

<u>Subject</u>	<u>Applications</u>	<u>First</u>	<u>Second</u>	<u>Third</u>
Pharmaceutics	: 60	1	1	1
Pharmaceutical Chemistry	: 33	1	1	1
Pharmaceutical Analysis	: 32	1	1	1
Pharmacology	: 33	1	1	1
Pharmacognosy	: 32	1	1	1
Pharmacy Practice	: 30	1	1	1
Biotechnology	: <u>22</u>	<u>1</u>	<u>1</u>	<u>1</u>
TOTAL	: 242	7	7	7

COLLEGE-WISE BREAK-UP

<u>Name of the college</u>	<u>Applications evaluated</u>	<u>Awards</u>
1. J. S. S. College of Pharmacy, Ooty	67	8
2. SRIPMS, Coimbatore	45	5
3. S. R. M. College of Pharmacy, Kattankolathur	23	*
4. Ultra College of Pharmacy, Madurai	22	*
5. Periyar College of Pharmacy, Trichy	13	3
6. K. M. C. H. College of Pharmacy, Coimbatore	12	*
7. Vinayaka Mission's College of Pharmacy, Salem	10	*
8. C. L. Baid Metha College of Pharmacy, Chennai	9	*
9. Padmavathi College of Pharmacy, Dharmapuri	9	*
10. P. S. G. College of Pharmacy, Coimbatore	9	2
11. Vel's College of Pharmacy, Chennai	7	1
12. Adiparashakthi College of Pharmacy, Melmaruvathur	4	2
13. J. K. K. Munirajah College of Pharmacy, Komarapalayam	3	*
14. Madras Medical College, Chennai	2	*
15. K. M. College of Pharmacy, Madurai	2	*
16. J. K. K. Natarajah College of Pharmacy, Komarapalayam	2	*
17. Sankaralingam Bhuvaneswari College of Pharmacy :	1	*
18. R. V. S. College of Pharmacy, Coimbatore	1	*
19. Arulmighu Kalasalingam College of Pharmacy, Sriviliputhur	<u>1</u>	<u>*</u>
TOTAL	242	21

RESULT

PHARMACEUTICS

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Mr. Arul Kumar B.	PSG College of Pharmacy, Coimbatore	Rs. 8,000/-
Second	Mr. Brito Raj S.	Periyar College, Trichy	Rs. 7,000/-
Third	Mr. Nithyananth M.	PSG College of Pharmacy, Coimbatore	Rs. 6,000/-

PHARMACEUTICAL CHEMISTRY

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Mr. Muralidharan V.	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. Padmaraj C. P.	SRIPMS, Coimbatore	Rs. 7,000/-
Third	Ms. Purnima S.	SRIPMS, Coimbatore	Rs. 6,000/-

PHARMACEUTICAL ANALYSIS

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Mr. Anil Dubala	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. Somasundaram M.	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 7,000/-
Third	Ms. Jothieswari D.	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 6,000/-

PHARMACOLOGY

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Mr. Austin Paul Joseph T.	SRIPMS, Coimbatore	Rs. 8,000/-
Second	Mr. Partha Deb Roy	JSS College of Pharmacy, Ooty	Rs. 7,000/-
Third	Mr. Patil Mohan Yashawant	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARMACOGNOSY

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Ms. Dhivya D.	Vel's College of Pharmacy, Chennai	Rs. 8,000/-
Second	Ms. Raveesha Peeriga	JSS College of Pharmacy, Ooty	Rs. 7,000/-
Third	Ms. Priyanka Dwarampudi	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARMACY PRACTICE

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Mr. Jose Francis	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. Vinoth Kumar. B. M.	Periyar College, Trichy	Rs. 7,000/-
Third	Ms. Sarumathy S.	Periyar College, Trichy	Rs. 6,000/-

BIOTECHNOLOGY

<u>Rank</u>	<u>Name</u>	<u>Institute</u>	<u>Amount</u>
First	Ms. Minu Mathew	SRIPMS, Coimbatore	Rs. 8,000/-
Second	Ms. Priya N.	SRIPMS, Coimbatore	Rs. 7,000/-
Third	Mr. Patel Viralkumar Laxmanbhai	JSS College of Pharmacy, Ooty	Rs. 6,000/-

The scholarship awards and certificates were distributed during the Valedictory functions of the 48th National Pharmacy Week Celebrations held at College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore on 30th November 2009 and also at Chennai by IPA, Tamilnadu Branch on 5th December 2009. The Secretary, Joint Secretary and other trustees of our Trust attended these meetings.

M. Pharm Scholarship 2009-2010

Profile of 1st Rank Projects

PHARMACEUTICS

Project Title: Brain targeted delivery of betulinic acid loaded nanoparticles for tumor

Name: Mr. Arul Kumar B.

PSG College of Pharmacy, Coimbatore

Guide Name: Dr. C. Vijaya Raghavan

PHARMACEUTICAL CHEMISTRY

Project Title: Synthesis of some novel 9-anilinoacridine derivatives and evaluation for their anticancer and antimalarial activity.

Name: Mr. Muralidharan V.

JSS College of Pharmacy, Udhagamandalam

Guide Name: Mr. R. Kalirajan

PHARMACEUTICAL ANALYSIS

Project Title: Bioequivalence studies of Cefotaxime proxitil and Clavulanic acid by LCMS method

Name: Mr. Anil Dubala

JSS College of Pharmacy, Udhagamandalam

Guide Name: Mr J. S. K. Nagarajan

PHARMACOLOGY

Project Title: Antidiabetic and Antioxidant activities of Cocos nucifera Linn. flower against streptozotocin-nicotinamide-induced Type 2 diabetes in rats.

Name: Mr. Austin Paul Joseph

Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide Name: Mr. A. T. Sivashanmugam

PHARMACOGNOSY

Project Title: Isolation and characterization of flavonoid from the leaves of *Wrightia tinctoria* (Roxb) and its evaluation of Anti-psoriatic activity.

Name: Ms. Dhivya D.

Vel's College of Pharmacy, Chennai

Guide Name: Dr. V. Ravichandran

PHARMACY PRACTICE

Name: Mr. Jose Francis

JSS College of Pharmacy, Udhagamandalam.

Project Title: "Influence of CYP2C19 Genetic Polymorphism on Pharmacokinetics of Sertraline in Indian Healthy Volunteers"

Guide Name: Mr. K. P. Arun

PHARMACEUTICAL BIOTECHNOLOGY

Name: Ms. Minu Mathew

Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Project Title: Virulence factors and Molecular level studies on multiple antibiotic and serum resistant *Escherichia coli* obtained from UTI.

Guide Name: Dr. S. Gopalakrishnan.



Prize distribution to the awardees at Chennai by Mr. Subburaj, IAS, Secretary H&FW Gov. of TN at IPA function on 5.12.2009



Prize distribution to the awardees at SRIPMS, Coimbatore by Dr. K. Chinnswamy Prof. Emeritus, JSS Collage, Ooty on 30.11.2009

EVENTS

National Elocution Competition 2009: A Report

The State Round of National Elocution Competition 2009 was held at Tamil Nadu Pharmaceutical Sciences Welfare Trust, Chennai on 5th November 2009 at 3.00 P.M on the topic ***“Regulatory role of Pharmacist in maintaining the safety and efficacy of medicines”***. 11 participants from various Pharmacy Colleges of Tamilnadu and 15 invitees participated in this event.

Ms. J. Priyadharisini, IIM. Pharm, College of Pharmacy, Madras Medical College, Chennai won the First Prize of Rs. 1,000/-, Mr. David Paul, I M. Pharm, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore won the Second Prize of Rs. 750/- and Ms. Manju Sree Madhu, I M. Pharm, K.M.C.H. College of Pharmacy, Coimbatore won the Third

Prize of Rs. 250/-. All the participants received the participation certificate.

The first two winners would be participating in the semifinal round at Sri Ramakrishna Institute of Paramedical Sciences Coimbatore and the winner of semifinal would be participating in the National round to be held during the 61st IPCA at Ahmedabad.

Dr. T. K. Ravi, Principal, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore was the National Convener and Dr. B. Jayakar, Principal, Vinayaka Mission's College of Pharmacy, Salem was the State co-coordinator for Tamilnadu of this National Elocution Competition.



48th NATIONAL PHARMACY WEEK CELEBRATIONS

College of Pharmacy, SRIPMS, Coimbatore

The College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences (SRIPMS), Coimbatore celebrated the 48th National Pharmacy week celebrations from the 25th to 30th of November 2009.

The chief guest, Mr. J. Jayaseelan, Director Novel therapeutics Pvt. Ltd., Chennai delivered Theme talk on ***“Make Pharmacy Your Career”***. Dr. Ravindra B. Ghooi delivered talk on ***“Role of Pharmacist in Clinical Research and on Ethics and Research methodology”*** and Mr. Sachin.C. Itkar gave a talk on ***“Landscape of Clinical Research Indian Scenario”***. Dr. Perumal, Principal J.K.K. Nataraja College of Pharmacy, Komarapalayam delivered a talk on ***“Natural Mucoadhesive drug delivery systems”*** and Dr. Sumita Singh, Assistant Professor, College of Pharmacy, SRIPMS, Coimbatore delivered a talk

on ***“DNA Vaccines - An update”***.

The Valedictory function and the IPA's National Elocution competition semifinal round were held on 30th November 2009. The function was presided over by Dr.N.Shanmugasundaram, Dean, Sri Ramakrishna Hospital and Prof. K.Chinnasamy, Prof. Emeritus, J.S.S College of Pharmacy, Ooty was the chief guest. Mr. N. Sreenivasen, Secretary and Mr. R. Narayanaswamy, Joint Secretary of Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai and Mr. T. B. Nair, Executive Secretary, IPA Central, Mumbai also participated in the function.

The scholarships for M. Pharm students in various specializations awarded by the Tamilnadu Pharmaceutical Sciences Welfare

Trust, Chennai were distributed to 15 students of J. S. S. College of Pharmacy, Ooty, SRIPMS, Coimbatore and P. S. G. College of Pharmacy, Coimbatore. The award included cash prizes and certificate, The prizes for the events conducted during the NPW celebrations were also distributed.

The semifinal round of IPA's National Elocution competition was also conducted. Twenty two contestants from eighteen states participated in the competition and spoke on the topic ***“Bench to Bedside Practice Challenging role of Pharmacist”***. Five students were selected who will participate in the final round competition during the 61st IPC, Ahmedabad

on 11th December 2009. To present their views on the topic ***“Pharma Vision in Education Keeping Pace with Challenging Professional Needs”***.



Indian Pharmaceutical Association, Tamilnadu Branch

The Valedictory function of the 48th National Pharmacy Week Celebration was jointly organized by Indian Pharmaceutical Association, TN Branch and Tamilnadu Pharmaceutical Sciences Welfare Trust on 5th December 2009 at Hotel Savera, Chennai. Mr. V. K. Subburaj, IAS, Principal Secretary, Health and Family Welfare Department, Government of Tamilnadu was the Chief Guest and Mr. M. Bhaskaran, Director of Drugs Control, Tamilnadu was the Guest of Honour.

Mr. R. Narayanaswamy, President, IPA, TN Branch welcomed the gathering of about 100 participants. Mr. J. Jayaseelan, Secretary, IPA Tamilnadu Branch and Director, M/s Novel Therapeutics Pvt. Ltd. and M/s. Delvin Formulations Pvt. Ltd. Chennai delivered the lecture on the Theme: ***“Make Pharmacy Your Career”***. It was followed by speeches by Mr. Bhaskaran, Mr. V. K. Subburaj and Dr. K. Chinnaswamy.

In recognition of his services rendered to the profession of Pharmacy, IPA, Tamilnadu Branch conferred **Pharmacist of the Year 2009**

award on Dr. V. R. Rajendran, Vice Chancellor, Vinayaka Mission's University, Salem. It was followed by award of scholarships by Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai to M. Pharm students based on their best projects.

The function concluded with vote of thanks by Dr. V. Ravichandran, IPA E. C. Member and Principal, Vel's College of Pharmacy, Chennai.



Mr. Subburaj IAS, Secretary H&FW Govt. of TN awarding to Pharmacist of the Year to Dr. V.R. Rajendran.

Faculty of Pharmacy, Sri Ramachandra University, Chennai

The Faculty of Pharmacy, Sri Ramachandra University, Chennai celebrated the 48th National Pharmacy Week on December 2nd 2009. Prof. Dr. Krishna Seshadri, Prof. & Head, Dept. of Diabetes, Endocrinology and Metabolism, Sri Ramachandra University delivered a lecture on ***"Newer targets and treatment paradigms in Pharmacotherapy of Diabetes"***. Vice-Chancellor, Prof. S. Rangaswami, Prof. K.V. Somasundaram, Dean of Faculties and Prof. S. Anandan, Dean, SRMC & RI graced the occasion. Prof. C. Uma Maheswara Reddy, Principal, Faculty of Pharmacy delivered the

key-note address on the theme ***"Make Pharmacy Your Career"***.



Padmavathy College of Pharmacy, Periyanaahalli

The 48th National Pharmacy Week was celebrated at Padmavathy College of Pharmacy, Periyanaahalli between 17th and 21st of November 2009. The celebrations were officially inaugurated on the third day by Dr. T. K. Ravi, Principal, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore. Mr. J. Jayaseelan, Secretary, IPA Tamilnadu Branch and Director, M/s Novel Therapeutics Pvt. Ltd. and M/s. Delvin Formulations Pvt. Ltd. Chennai delivered a speech on the theme: ***"Make Pharmacy Your Career"***.

During the Valedictory function, Mr. M. G. Sekar, Chairman of the college delivered the Presidential Address and Dr. V. R. Rajendran, Vice Chancellor of the Vinayaka Mission's University released the college magazine and also delivered a speech on Pharmacy Education in Current Society and on the position of India in Global Pharmacy. Dr. Narayanan, Joint Director of Medical Education (Pharmacy), Chennai and

Dr. B. Jayakar, Dean, College of Pharmacy, Vinayaka Mission's University addressed the gathering. Dr. S. Gopalakrishnan, Professor Emeritus, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, Mr. K. G. K. Chowdary, Advisor and Mr. B. V. Vijay Kumar, CEO of the institute also participated in the meeting.



Vels College of Pharmacy, Chennai

The 48th National Pharmacy Week celebration was inaugurated on 23rd Nov 2009 at Shivalaya auditorium, Vels University, Chennai by Founder Chancellor Dr. Ishari K. Ganesh. Mr. V.Suresh delivered a lecture on the theme ***“Make Pharmacy your career”*** and highlighted about various career opportunities in Pharmacy. In clinical aspects, Dr. A. V. Srinivasan, Former Professor of Neurology, Madras Medical College, Emeritus Professor, The TN Dr.MGR Medical University, Chennai gave a lecture on ***“Ten steps Approach to Epilepsy”***.

On the Valedictory day, Prof. Dr. N. Raaman, Director, Centre for Herbal Sciences, University

of Madras, Chennai delivered a lecture on ***“Screening of Medicinal Plants-An Approach”***.



College of Pharmacy, Madras Medical College, Chennai

The 48th National Pharmacy Week was celebrated at College of Pharmacy, Madras Medical College, Chennai on 27.12.2009. Dr. S. Vinayagam, Director of Medical Education and Dr. N. Narayanan, Joint Director of Medical Education were Guests of Honour. The lecture on the theme ***“Make Pharmacy Your Career”*** was delivered by Mr. R. Thiruvengadam, Joint Managing Director, Tablets (India) Pvt. Ltd., Chennai, emphasizing on the career prospects and immense research potentials in Pharma industry across the globe.

In the afternoon, the final round of state-level inter-collegiate Quiz Competition was conducted. Nine teams, selected from 139 teams at the preliminary rounds conducted at 3 zones (Chennai, Coimbatore and Madurai), participated in the finals. First prize for Rs.

15,000/- was bagged by students of Madurai Medical College, Madurai, second prize of Rs. 10,000/- by Vel's College of Pharmacy, Chennai and third prize of Rs. 5,000/- was won by College of Pharmacy, Madras Medical College.



Vinayaka Mission's College of Pharmacy, Salem

The Vinayaka Mission's College of Pharmacy, Vinayaka Mission's University celebrated 48th National Pharmacy week on 27.11.09 at the college premises. Dr. C. Mani, Joint Director of Health Services was the Chief Guest and Dr. P. S. Manoharan, Medical Superintendent of Vinayaka Mission's Kirupananda Variyar Medical College was the Guest of Honour. An elocution competition on the theme "Make Pharmacy Your Career" was conducted.



Periyar College of Pharmaceutical Sciences for Girls, Trichy

The 48th National Pharmacy week was celebrated at Periyar College of Pharmaceutical Sciences for Girls between 15th and 21st November 2009. The celebrations began with a National Seminar on the topic "***Current Trends in Community Pharmacists for Working Pharmacists***". The inaugural address was given by Mr. T. Ilango, Registrar, Tamilnadu Pharmacy Council, Chennai. Mrs. M. Chitra, Pharmacist (Special Grade), Annal Gandhi Memorial Government Hospital, Trichy delivered a lecture on "***Role of Pharmacist in Community Health Care***". Lecture on the Theme "Make Pharmacy Your Career" was organized at various schools. As part of the celebration, pamphlets were distributed to the public and a Pharma rally was also organized.



The Registrar, Tamilnadu State Pharmacy council, speaks on the occasion of one day workshop for working pharmacists on 15.11.09

61st IPC, Ahmedabad

The 61st Indian Pharmaceutical Congress (IPC) was organized by All India Drugs Controller Officers' Confederation (AIDCOC) and Indian Pharmaceutical Congress Association (IPCA) from 11th to 13th of December 2009 at Nirma University of Science and Technology, Ahmedabad. This year, the theme of the Congress was "Building Trust in Safety and Efficacy of Medicines". Mr. S. W. Deshpande, President IPCA was the President of the 61st IPC. The congress was attended by more than 8,000 delegates. An

exhibition, displaying Pharma manufacturing machineries, analytical instruments and book stall of pharmacy book dealers was organised at the venue by Federation of Indian Chambers of Commerce & Industry (FICCI). Wide ranging topics from scientific, regulatory and technology to professional were covered to meet the sectoral interests of all. Shri. Sreenivasen, Secretary and Shri. R. Narayanaswamy, Joint Secretary of the Trust were nominated and attended the Congress.

Felicitation to Mr. M. Bhaskaran, Director Drugs Control, Tamilnadu

The Pharmaceutical Manufacturers' Association of Tamilnadu and Indian Drug Manufacturers' Association organised a function to felicitate Mr. M. Bhaskaran, Director of Drugs Control, Government of Tamilnadu for his elevation to the post of Director of Drugs Control on 23rd December 2009 in Chennai.



Inaugural speech by Principal Secretary, Ministry Health & Family Welfare, Government of Tamil Nadu

Mr. V K Subburaj, Commissioner & Principal Secretary, Ministry Health & Family Welfare, Government of Tamil Nadu was the chief guest of the 48th National Pharmacy Week Celebration organised by Indian Pharmaceutical Association, TN Branch on 5th December 2009 in Chennai.

In his address, he said that although India has good quality drugs, it has to refine the methods of drug discovery for the benefit of the society, as the country is encountering a shortage of good drugs for chronic diseases and viral diseases. More researches have to be done in these areas, and he also emphasized stricter quality control of the drugs manufactures into his country.

Mr. Subburaj said after India's independence, one of the great achievements the country could win is the self-sufficiency in drugs, like that of

food grains. But the modern pharmacists should understand the scope and potential of the growing pharmaceutical industry. He exhorted the drug inspectors and other pharmacists presented in the seminar to educate the younger generation about the scope of Pharma sector and the job opportunities therein.

While highlighting the scope of career opportunities, he said in the country more than five lakh chemists & druggists are working, out of which 40,000 are in Tamil Nadu. In India, 20,000 registered Pharma manufacturing units are functioning. Among them, 250 units are big ones and 8000 units are small ones. These units can provide immense job opportunities for pharmacy graduates. He also said that the need of setting up of a separate Directorate of Pharmaceutical Education will be looked into.

TRAINING / PLACEMENT FOR PHARMACY PROFESSIONALS

Tamilnadu Pharmaceutical Sciences Welfare Trust is creating a database for the placement of graduates and post-graduates in Pharmacy who require job opportunities in Pharmacy field like academics/ industries (production, QA & QC) / marketing / research and regulatory affairs, etc.

Persons who are fresh graduates or experienced in pharmacy field may forward their CV clearly mentioning the area if interest to this Trust by email to pharmjobs2010@yahoo.in.

Fourrts WINS

OUTSTANDING EXPORT PERFORMANCE AWARD



S.V.Veerramani CMD, Raghu S.Kallur GM (IB) & Kaushik Bhammar AGM (IB) of Fourrts (India) Laboratories Pvt Limited receiving the Outstanding Export Performance Award 2008-09 of Pharmexcil, Govt. of India from Hon. (PROF.) Peter A Nyong'O - Minister of Health, Kenya on 25th Sept '09 at Hyderabad



NEWS

Rs. 300- Cr push for device manufacturing

The Government has announced a Rs 300-crore initiative to promote domestic manufacture of medical devices such as stents, catheters, heart valves and orthopaedic implants that will lead to lower prices of these critical equipment, making them accessible to millions of patients across the country.

The department of Pharmaceuticals is in talks with state governments for developing clusters to manufacture medical devices that will ensure safe, effective and clinically-beneficial medical technologies for the domestic and export markets, an official in the ministry of chemicals and fertilizers said.

“We have finalized a project with the Gujarat government. The first cluster in the state is likely to be ready by the end of 2009,” the official said on condition of anonymity. The Rs.10,000-crore domestic medical devices industry manufactures low-technology products and exports over 70% of its output. So, critical medical devices such as stents, catheters, heart valves and orthopaedic implants have to be imported in huge volumes. The bill for such imports touched Rs 7,500 crore last year.

The government's drive will lead to development of the medical devices industry in the country, resulting in lower prices of these

Critical products. The move will benefit millions of patients in the country as sophisticated equipment is a major cost component of healthcare in private hospitals. Most patients cannot afford less-invasive procedures such as keyhole surgery due to high cost of imported catheters and other devices that inflate the cost of treatment.

Domestic production of medical devices is expected to significantly bring down their prices, the official said. The medical devices market is dominated by multinational corporations and their joint ventures, including Hewlett Packard, Wipro-GE, Toshniwal Brothers and Medi Systems.

Source: *The Economic Times*, 5th October 2009



Medical Colleges told to keep close watch on medicines

In a bid to tighten quality checks on medicines, the health ministry plans to make it mandatory for all medical colleges and hospitals to report unwanted and negative responses to medicines available in the Market. The ministry has also asked the Medical Council of India (MCI) to approve only those medical colleges in future that have such a system in place, a health ministry official said.

The move is significant because despite a ban across the world, many medicines with severe side-effects and adverse reactions continue to be legally available in India. "This is possible because of the absence of a robust adverse drug reactions (ADRs) reporting system, the Drugs Controller General of India (DCGI) often do not have enough reports on the efficacy of drugs sold in the country," the official said. While adverse drug reactions provide crucial inputs for life-saving medicines, its awareness level among hospitals is poor. Medical experts say that a very small number of adverse drug reactions are reported by hospitals in the country.

Initially, the government plans to identify ten public medical colleges in each zone north, south, east and west, the official said. According

to him, the government will set up a model pharmacovigilance centre in each of these ten hospitals. Later on, all the hospitals will be asked to follow the set path to build similar centres.

This would enable the drug regulator, the DCGI to keep a stringent check on the efficacy of medicines and their side-effects, a health ministry official said.

Medical experts say that there is an immense need for reporting adverse drug reactions and post-marketing surveillance, as medicines are evaluated for toxicity in a limited group of patients before marketing. "The limitations of clinical trials means that when a drug is first marketed, much may be known about its efficacy, while relatively a little may be known about its safety," said a medical expert.

Once reported, the DCGI will analyse these adverse drug reactions and data related to important medicines would also be posted on its website, the official said.

Source: *The Economic Times*, 12th October 2009



Indian Pharma exports may get safe passage through EU

Pharmaceutical exports from India are likely to be promised safe passage by the European Union after India took up the issue following seizure of two consignments while in transit through the region. The EU had taken this extreme step following complaints made by the patent holders of the medicines being shipped.

The EU is in talks with the Indian government on making changes in its customs rules to ensure that such seizures, which are in violation of international intellectual property rules, do not happen in the future. The Dutch government, which is taking a lead in this matter as the seizures happened at the Schipol airport in Netherlands, has asked India about the possible directives to the customs department to prevent such seizures, a senior commerce department official has said. The move follows India's threat of dragging the EU to the WTO for violation of the Trips agreement on intellectual property and diverting its air cargo away from Schipol.

Speaking to ET, the official said that the EU had realised that the seizures were against the Trips agreement as the life-saving medicines were being exported and India had every right of selling it to a developing country. "If we ask for establishment of a panel at the WTO, the EU

could be in trouble. It is in their interest that they sort the issue out with us outside the WTO," the official said.

The issue will also be discussed by EU trade commissioner Catherine Ashton and Commerce & Industry minister Anand Sharma during the India-EU business summit in New Delhi on Friday. "We told them that it was for them to decide. We simply don't want such seizures to happen in future as it leads to loss of money, time, trust and business," the official said. India has informally communicated to the Netherlands that if the customs regulations are not modified it would start diverting its cargo through other countries which would lead to a revenue loss for the country.

The Dutch authorities confiscated anti-HIV drugs manufactured by Aurobindo Pharma on the way to Nigeria at the Schipol airport in March this year and high blood pressure drugs manufactured by Dr. Reddy's lab on its way to Brazil in January and sent it back to India. India's exports of drugs, pharmaceuticals and fine chemicals for the year 2008-2009 stood at Rs 39,538 crore, registering a growth of about 29% over the previous year.

Source: *The Economic Times*, 4th November 2009



Aurobindo gets USFDA nod for hypertension drug

Drug firm Aurobindo Pharma on Thursday said it has received final approval from the US health regulator for Perindopril Erbumine tablets, used for the treatment of hypertension. Perindopril Erbumine tablets are in the strength of 2mg, 4mg, and 8mg, Aurobindo said in a filing to the Bombay

Stock Exchange. The product would be launched shortly, it added. Aurobindo has a total of 109 ANDA approvals (81 final and 28 tentative approvals) from USFDA.

Source: *The Economic Times*, 13th November 2009

Drug cos need to tighten belts to meet FDA norms

Indian generic drug makers could face more actions from the USFDA unless they maintain high quality requirements of the regulator, which has tightened norms for granting permission to sell medicines in the US.

The USFDA has the task of regulating and supervising the safety of drugs and cosmetics in the US. "In recent times, the US FDA (Food and Drug Administration) has increased its focus on the quality and safety of the drugs. India with large number of generic companies, many of which supply to the US market, will witness continuous monitoring by the US FDA," KPMG India, a consultancy firm, Corporate Finance Associate Director Sanjay K Singh said.

The generic drugs market in the US is estimated to be over \$30 billion and it is the biggest market for Indian companies. In a recent move, the US health regulator has stepped up inspection and compliance activity after increasing its funding for the purpose during the current and the next year.

Besides this, it has also reduced the responding time to 15 working days from 30 days for companies getting notices for deficiency in compliances. "India is a recognized and important supplier of generic medicine to the world so it will have an impact if we do not align totally in this direction," Organisation of Pharmaceutical Producers in India President Ranjit Shahani said.

They want violative inspection results to be taken seriously in order to protect the consumer, Shahani added.

Expressing similar views, Ranjit Kapadia, Vice President (Institutional Research) at HDFC Securities, said the US authorities are under tremendous pressure to reduce the cost of healthcare and this led to increasing import of generic medicines from countries like India and China.

"They have to make sure that any drug entering into their country is up to the mark," Kapadia added. The US FDA has been clamping down on pharma firms which are not complying with its requirements. Last year, it had banned 30 generic drugs from Ranbaxy Laboratories from selling in the country for not complying with its good manufacturing practice norms.

A significant tightening in implementation of regulatory requirements has caught several companies off guard, making quality and system adherence topmost priority, "Sun Pharmaceutical Chairman Dilip Shangvi told the company's shareholders at its recently held Annual General Meeting.

Other industry experts, however, ruled out that only Indian companies are being targeted by the US FDA. "FDA activities are not specifically directed towards Indian companies. They are getting tough on every one including US companies and no lobbying activities are behind this," Ernst & Young partner M. Muralidharan Nair said.

Source: *The Economic Times*, 21st September 2009



FORTHCOMING EVENTS

IPA Convention 2010

The Indian Pharmaceutical Association TN Branch is organising IPAC convention 2010 on 12th, 13th and 14th of March 2010 at Sri Ramachandra University, Chennai. The theme of the convention is: ***"India Surging Forward as the Global Pharma Destination"***.

Local Organising Committee:

Chairman: Mr. S. V. Veerramani **Co-Chairmen:** Mr. R. Narayanaswamy, Mr. R. Sabapathy
Mr. M. M. Yousuf, Dr. V. Ravichandran
Secretary: Mr. J. Jayaseelan **IPA Co-coordinator:** Mr. C. Gopalakrishna Murthy
Treasurer: Mr. Rajesh H. Bhandari **IPA Convention Coordinator:** Dr. K. Chinnaswamy

Satellite workshop on **HIV / AIDS** by Commonwealth Pharmaceutical Association (CPA) and on **Stability Testing for Global Submission** by IPA Regulatory Affairs Division and IPA, Tamilnadu Branch in association with the American Association for Pharmaceutical Scientists (AAPS) will be organized on 12th and 13th March 2010.

The registration details are as follows:

Delegate type	For IPA Convention 2010 13 & 14 March 2010		For Satellite workshop on Stability Testing & IPA Convention 12, 13 & 14 March 2010		For CPA IPA workshop on HIV/AIDS & IPA Convention 12, 13 & 14 March 2010	
	On or before 15th Feb 2010	Between 16th Feb to 5th March 2010	On or before 15th Feb 2010	Between 16th Feb to 5th March 2010	On or before 15th Feb 2010	Between 16th Feb to 5th March 2010
For IPA members	1,000/-	1,500/-	3,000/-	3,500/-	1,500/-	2,000/-
For non-IPA members	1,500/-	2,000/-	3,500/-	4,000/-	2,000/-	2,500/-
For students	750/-	1,000/-	1,500/-	2,000/-	1,000/-	1,500/-

Contact Details:

LOC Secretariat

The Indian Pharmaceutical Association

C/o Tamilnadu Pharmaceutical Sciences Welfare Trust

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Web: www.ipapharma.org



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COURSES OFFERED

D. Pharmacy	2 Years
B. Pharmacy	4 Years
B. Pharmacy (Lateral Entry)	3 Years
M.Pharmacy	2 Years

Pharmaceutics

Pharmaceutical Chemistry

Pharmacognosy

Pharmacology

Pharmaceutical Analysis

Pharm.D	6 Years
Pharm.D (Post Baccalaureate)	3 Years
Ph.D Programme	
Full Time	3 Years
Part Time	4 Years

Prof. Dr. B. Jayakar
Principal

Prof. Dr. V.R.R. Rajendran
Vice-chancellor