Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 20 Oct.-Nov.-Dec.- 2013

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NEW TRUSTEES AND GOVERNING BODY MEMBERS OF TNPSWT

There are THREE main Trusts in the Pharma field in Tamilnadu namely, Tamilnadu Pharmaceutical Sciences Welfare Trust (TNPSWT), Tamilnadu Indian Pharmaceutical Association Trust (TANIPA) and Tamilnadu Pharmaceutical Trust (TPT). In order to attain the goal of various activities and also improve the Pharma profession uniformly, the Trust TANIPA & TPT donated funds to TNPSWT.

In order to co-ordinate the activities, the number of Governing Body Members were increased from 9 to 18 after inducting new Trustees, for which necessary formalities obtained from Government authorities.

The lists of Trustees of TNPSWT after the joining of new Trustees are as follows :

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EDITORIAL

Dear Readers,

We are happy to publish and release 20th issue of our Pharm Web news letter October - December 2013. We are happy to announce that our Trust Chairman Shri. S. V. Veerramani, Chairman and Managing Director of M/s. Fourrts (India) Laboratories Pvt Ltd., has been elected as President of Indian Drugs Manufacturers Association. In this news letter three articles namely "Global Expectations for Pharmacy Education" by Mr. Michael Rouse, Asst Executive Director, ACPE, "Trade Mark & Its Relevance by Mr. V. Natarajan, Deputy Registrar - Trade Mark & GI and "Multiparticulate Technology: Formulation and Processing Consideration" by Dr. Jayesh Parmar, Formulation Technology Manager, Colorcon South Asia Manager, Goa are included. Important Gazetted notifications like Regulatory Requirements for Import, Manufacture and Clinical Trial of Phytopharmaceuticals, Requirement of qualified person and labeling requirements for Medical Devices, New Schedule H1 Drugs, definition of loan licence and Drugs Price Control Order for various Drug Formulations are published in this issue. We are happy to inform the readers that various other Trusts like TANIPA and TPT are merged with our Trust in order to stream line conducting various programs and workshops for the improvement of our profession. Our Trust awarded scholarships for 24 students from M.Pharm & Pharm D courses. We also conducted Essay competition for the final year B.Pharm students and awarded prizes for the winners who ranked highest mark in the competition. The details of awards are published in this issue for the reader's benefit. Our IPA TN Branch celebrated Pharmacist Day and National Pharmacy Week in a grand manner. We have published various programmes organised by them on these celebrations in this news letter. Various important events, information and news are published in this news letter including rejection of Central Drug Authority Bill by Parliament Standing Committee. We like to bring it to our readers that our Trust is organising an Industrial oriented Training program on Quality Control of Drugs and Pharmaceuticals for the fresh B.Pharm / M.Pharm graduates by end of January 2014 for a period of 1 month. We have already sent a letter along with training program brochure to all the pharmacy colleges in Tamilnadu. We request all the principles of college of pharmacy to forward the names of the candidates before first week of January 2014.

I hope the readers may be benefited by this issue with all news items and other technical informations.

With best Regards,

R. NARAYANASWAMY

Chief Editor

With best compliment from

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ARTICLES

GLOBAL EXPECTATIONS FOR PHARMACY EDUCATION

By

Michael Rouse

Assistant Executive Director, Professional Affairs and

Director, International Services, ACPE

Lecture Delivered at President's Symposium, 64th IPC Chennai, on 7th December 2012

Overview of Presentation

- *Some Context*
- *Who has Expectations? Who are the Stakeholders?*
- *What's Changing? Who/What Drives Change?*
- *The Scope of Pharmacy/Pharmacist Practice and Pharmacy Education*
- *Expectations for Structure, Process and Outcomes*

Providing Some Context

- *Unprecedented change in pharmacy practice and education*
- *New technologies, knowledge, skills, attitudes, and values (KSAV) to be embraced and achieved by graduates*
- *Global diversity:*
  - *what a "pharmacist" is and does*
  - *how pharmacists are perceived and valued by society*
  - *pharmacy education*
  - *pharmacy support workforce*

Future Vision of Pharmacy Practice*

"Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

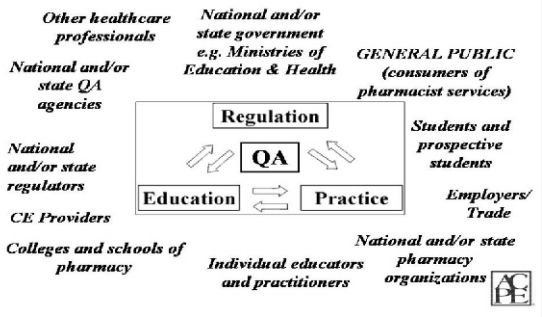
2015 Vision Statement of the Joint Commission of Pharmacy Practitioners (JCPP), USA

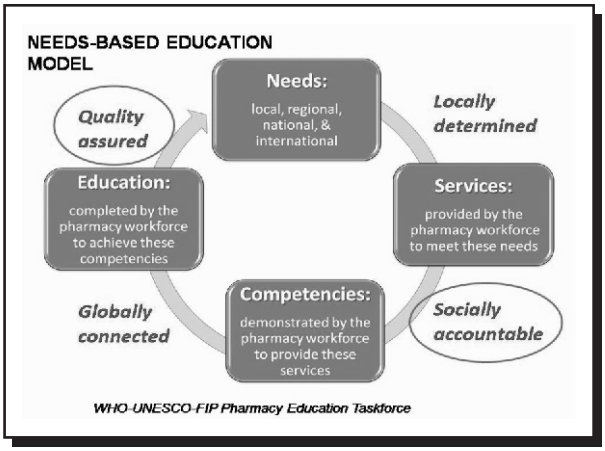
Providing Some Context

- *Traditional product-focused roles well understood; expanded roles not yet fully understood and valued*
- *Diversity of roles has likely caused confusion, impeded advocacy efforts, slowed implementation of new practice models*
- *Growing awareness of enhanced roles that pharmacists can play in improving the safety and outcomes of medication use by:*
  - *Governments and other funders of health care*
  - *Patients*
  - *Other healthcare professionals*

Stakeholders

- *Stakeholders exist at multiple levels:*
  - *Local*
  - *National*
  - *Regional*
  - *International/Global*
- *Within and external to the profession*
- *Stakeholder <u>needs</u> will generally determine stakeholder <u>expectations</u>*





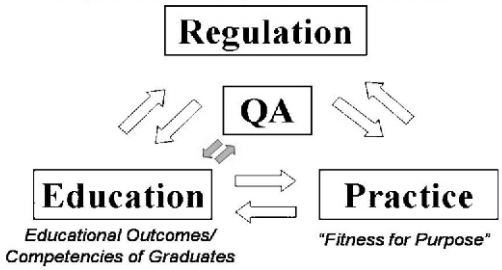
Social Accountability

The obligation of pharmacy schools to direct their education, research and service activities towards addressing the priority health needs of the community, region, and/or nation they have a mandate to serve (the "stakeholders"). The priority health needs are to be identified jointly by governments, healthcare organizations, health professionals and the public.

Source: ACPE Policies and Procedures for Certification of Professional Degree Programs in Pharmacy. Adapted from WHO 1995 and ASPIRE 2012.

The Role of Quality Assurance

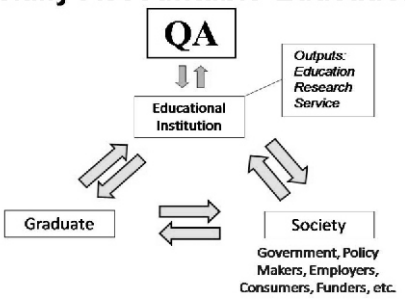
Scope of Practice/Competence/Public Protection



The Role of Quality Assurance

- *By setting the "standard" the quality assurance body ultimately defines and sets the expectation.*
- *QA standards and system must account for all stakeholder needs; must, therefore, provide for input from the public (society)*
- *QA must be a profession-wide process and have profession-wide "ownership"*

Socially Accountable Education



The Mission of QA Agencies

ACPE Mission: *To assure and advance excellence in education for the profession of pharmacy*

International Services Program Mission: *Promote, assure, and advance the quality of pharmacy education internationally to improve patient care through safe and effective medication use.*

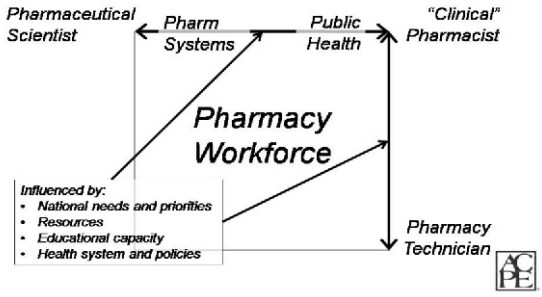
Why a Global Expectation?

- *Increasing global connectivity*
- *Mobility of pharmacists*
- *Global goals for healthcare delivery and patient/population outcomes*
- *Global advocacy efforts and collaboration (WHO, FIP, etc.)*

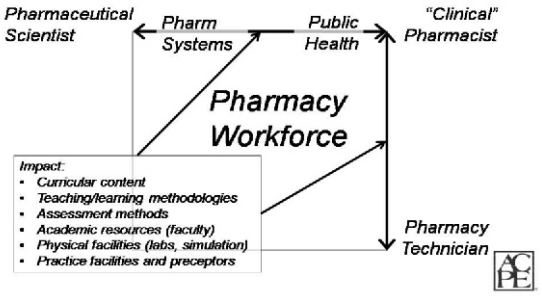
A Global Expectation

Using a "Needs-Based Education Model" can we define "Pharmacist" globally, agree on the appropriate competencies, and identify levels of performance for each competency area?

Continuum of Needs



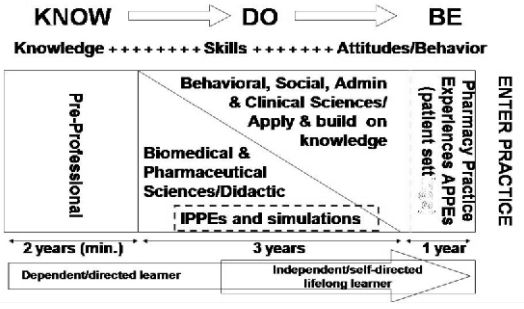
Continuum of Competencies



Competency-Based Educational Models

- *Outcomes-Based Education*
- *Curriculum based on desired competencies to be achieved by graduates, not on content/available expertise*
- *Curricular philosophy and model (e.g. teaching/learning and assessment methodologies) determined by competencies to be achieved*

The PharmD Degree (US Model)



Can One "Pharmacist" and One "Pharmacy Degree" Meet all these Needs?

Some educational trends:

- *Different degree options*
  - *United States*
  - *India*
- *One Degree with Tracks*
  - *ITB, Indonesia*

Self-Directed Lifelong Learning

No professional education can be expected to deliver all that a pharmacist will ever need to know.

A key competency to be achieved and assessed is that of self-directed lifelong learning.

This competency must be developed before graduation and continue to be supported in practice.

A Global Competency Framework?

Four competency domains:

- *Pharmaceutical Care*
- *Pharmaceutical Public Health*
- *Organization and Management*
- *Professional/Personal*

Standards or Standardization?

- *Quality must be determined on the basis of evaluation against agreed standards*
- *Standards should be developed and adopted through profession-wide consensus*
- *Compliance with accreditation standards is not necessarily intended to imply or ensure standardization:*
  - *in all aspects of the degree program*
  - *mission, structure, and outcomes of the school of pharmacy*

Standards or Standardization?

Accreditation standards should allow some degree of flexibility for schools of pharmacy:

- *how they achieve the desired outcomes for graduates*
- *other mission-related aspects*

Pillars of Quality

- **Outcomes**
  What you should achieve or produce (e.g., defined educational outcomes/competencies, other desired outcomes – research, service)
- **Structure**
  What you need to have in place (e.g., organizational structure and administration, physical facilities (incl. for practice experiences), resources, mission & goals)
- **Process**
  What you need to do (e.g., policies and procedures, planning, curriculum, teaching methodologies, assessment and evaluation)

Other Expectations Driven by Accreditation

- *Educational institutions are expected and required to provide more information, including student performance data, to the public*
- *Opportunity for all to provide input in the accreditation (self-study) process, e.g., students, faculty, preceptors, practitioners, regulators, public*

Other Expectations Driven by Accreditation

- *Development of a culture of assessment (measuring outcomes), self-assessment (achievement of all mission-related goals), and continuous quality improvement (CQI)*
- *Self-identification of areas of non-compliance and other areas needing improvement; commitment to resolution of areas of non-compliance in a timely fashion*

Summary and Key Principles

- *Societal/stakeholder needs determine expectations ("social accountability")*
- *Needs – and, therefore, expectations - exist at the local, national, regional, and global levels*
- *With increasing freedom of movement for people, products and services, calls for clearer definition and increased transnational standardization are becoming more widespread*

Some Key Global Expectations

- *Recognize national and regional differences but expect greater consistency in:*
  - *what a "pharmacist" is and does*
  - *educational models*
- *Move to outcomes-based education (curricular design, delivery, assessment, etc.)*
- *Core competencies to be identified*

Some Key Global Expectations

- *Universities and schools of pharmacy must be socially accountable and committed to continuous quality improvement*
- *Accreditation standards must provide a level of standardization and consistency (especially in terms of what graduates are competent to do) but allow for institutional flexibility and unique aspects of program and mission*

With best compliments from :

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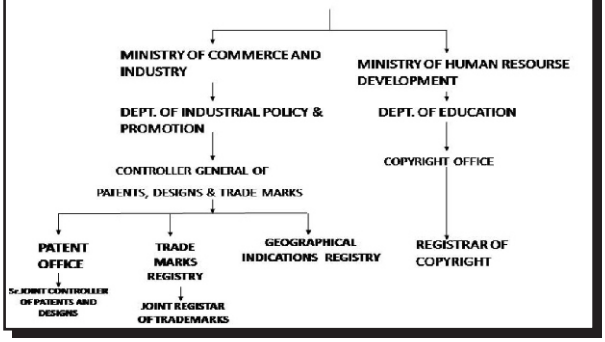
TRADE MARK & ITS RELEVANCE

By
Shri. V. Natarajan
Deputy Registrar – Trade Marks & GI
Lecture delivered at IPR Seminar conducted by IPA, TN on 27th July 2013

Protection Of Intellectual Property In India
(Patents, Designs, Trade Marks, GI & Copyrights)



Why to Care ?

Trademarks & Consumers.

To identify, differentiate products.

Economically efficient communication tools.

Transcend language and borders – Trans border Reputation.

Trademark registration is a bargain.

Trademarks & Consumers

- **Trademarks:**
  - **Help & aid - capture the consumer's attention**
    - **(a). Selection and/or rejection of the product**
    - **(b) Consistency and quality of the product**
  - **Concept of (1). Man of average intelligence and**
    - **(2). Imperfect recollection**
  - **Developing brand image for a company or product**
  - **A trade mark is used as a marketing tool so that customers can recognize the product of a particular trader.**

▪Branding plays a pivotal role in driving a consumer's purchasing decision.

▪Consumers may be willing to pay more for goods and services associated with well-known brands.

Economically efficient communication tools.

- A single word or phrase, a design, a slogan, a product configuration, or other indicator can convey a lot of information when used as a mark.

IBM Godrej WIPRO

Trademarks transcend language and borders - Trans border Reputation..

- Trademarks can work effectively across borders, cultures, and languages.
  - Famous marks are recognizable even by consumers who have a different language and alphabet than the source company.

adidas SONY

Trademark registration is a bargain.

- Costs of government fees and legal services to obtain and maintain trademarks are:
  - relatively low compared to other types of Intellectual Property;
  - typically dwarfed by advertising costs; and
  - extraordinarily low per consumer reached.

TRADEMARKS

- A trade mark is any sign which can distinguish the goods of one trader from those of another. Sign includes, words, letters, numerals,
- logos, pictures, or a combination of these.

•A trade mark is used as a marketing tool so that customers can recognize the product of a particular trader.

•To register a trade mark , the mark must be:-

•distinctive, **and** not deceptive, or contrary to law or morality, **and** not identical or similar to any earlier marks for the same or similar goods.

TRADE MARKS

- DEFINITION OF MARK AND TRADE MARK
- SECTION 2(1)(m) DEFINES A MARK TO INCLUDE A DEVICE, BRAND, HEADING, LABEL, TICKET, NAME, SIGNATURE, WORD, LETTER, NUMERAL, SHAPE OF GOODS, PACKAGING OR COMBINATION OF COLOURS OR ANY COMBINATION THEREOF
- SECTION (2) (1) (zb) STATES **TM** MEANS A MARK CAPABLE OF BEING GRAPHICALLY REPRESENTED **AND** CAPABLE OF DISTINGUISING GOOD/SERVICES OF ONE PERSON FROM OTHERS AND
- USED IN THE COURSE OF TRADE TO SHOW A TRADE CONNECTION BETWEEN GOODS/SERVICES AND THE PROPRIETROR OF THE MARK

TRADEMARKS

➢How to select a Trade Mark ?

1. A word, letter or any combination thereof and simple in design.
2. If it is a word it should be easy to speak, spell and remember.
3. The ideal word for a trade mark is an invented or coined word

4. Words which are laudatory or which directly describes the character or quality of the goods should not be adopted.

5. Geographical names connected with the reputation or quality of the goods for which registration is sought should not be adopted.

➢Are all Trade Marks registrable ?

➢Not possible to register a mark which is confusing with a trade mark of another trader or a trade mark which describes the character or quality of the goods. The mark should not conflict with a trade mark already registered or pending registration in respect of similar goods.

Under the Indian trademark law the following are the types of trademarks that can be mainly registered:

- PRODUCT TRADEMARKS: are those that are affixed to identify goods.
- SERVICE TRADEMARKS: are used to identify the services of an entity, such as the trademark for a broadcasting service, retails outlet, etc. They are used in banking, insurance, real estate, transport, supply of electricity or energy, boarding, lodging, entertainment, construction, advertisement, etc.
- CERTIFICATION TRADEMARKS: are those that are capable of distinguishing the goods or services in connection with which it is used in the course of trade and which are certified by the proprietor with regard to their origin, material, the method of manufacture, the quality or other specific features
- COLLECTIVE TRADEMARKS: are registered in the name of groups, associations or other organizations for the use of members of the group in their commercial activities to indicate their membership of the group.
- HOUSE MARK can be used on all products of a company- example dabur, pfizer, alembic, tatas, cadbury (bournvita, éclair, diary milk), parle, tvs, etc.

Classification of Goods and Services

- Almost all jurisdictions including India employ a classification system in which goods and services have been grouped into classes for registration. Most countries follow the same classification system, namely the International Classification of Goods and Services, (NICE) which consists of 34 classes of goods and 11 classes of services.

What types of things can be protected by trademark laws?

- Word marks
- Device marks
- Shape of goods, Packaging,
- Composite marks
- Brand, Heading, Label and Ticket,
- Signature, Letter, Numeral
- Combination of colours or any combination
- Certification marks – Section 2 (1)(e) The Trade marks Act, 1999
- Collective marks – Section 2 (1)(g) The Trade marks Act, 1999

Overview of Trademark Protection:
Bases of trademark protection.

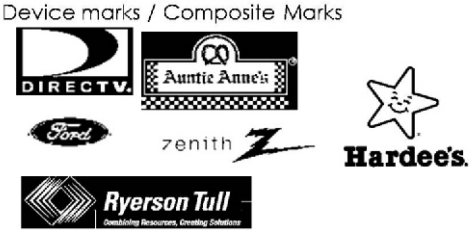
- Property right
  - Ownership in the mark is a property right similar to owning real estate or other "real property"
- Consumer protection
  - Protection of the consumer from confusion as to source and quality

What types of things can be protected by trademark laws?

- Word marks
  - **ZENITH**
  - **Wipro**
  - **Godrej**
  - **FORD**
  - **COCA COLA**

What types of things can be protected by trademark laws?

- Device marks / Composite Marks



What types of things can be protected by trademark laws?

- Certification marks
  - ***"Certification trade mark" means a mark capable of distinguishing the goods or services in connection with which it is used in the course of trade which are certified by the proprietor of the mark in respect of origin, material, mode of manufacture of goods or performance of services, quality, accuracy or other characteristics from goods or services not so certified and registries as such under Chapter IX in respect of those goods or services in the name, as proprietor of the certification trade mark, of that person;***

FEW EXAMPLES OF CERTIFICATION MARKS

What types of things can be protected by trademark laws?

- Collective marks
  - ***A mark means a trade mark distinguishing the goods or services of members of an association of persons [not being a partnership within the meaning of the Indian Partnership Act, 1932 (9 of 1932)] which is proprietor of the mark from those of others;***

FEW EXAMPLES OF COLLECTIVE MARKS

IMPORTANT PROVISIONS OF THE NEW TRADEMARK LAW

- Inclusion of services
- Classes of goods extended to 45 international categories
- Registration extended to 10 years
- Special protection to "well known trade name"
- protection across goods if the brand name is reputed

Procedures for Trade Mark Registration

- **Filing of trade / service mark application for the registration of trade / service mark.**
- **Issuance of official receipt.**
- **Issuance of numbered additional representation.**
- **Issuance of examination report.**
- **Filing of reply to the examination report.**
- **Hearings.**
- **Advertisement.**
- **Registration.**

ABSOLUTE GROUNDS FOR REFUSAL

- Not being distinctive;
- Incapable of graphical representation;
- Consisting exclusively of marks and indications to designate kind, quality, quantity, intended purpose, values, geographical origin etc.;
- Mark being identical with or deceptively similar to a registered TM in respect of same goods or services.

Contd.

- A mark if it consists exclusively of the shape of goods which
  - results from the nature of goods themselves;
  - is necessary to obtain a technical result;
  - which gives substantial value to the goods (difficult to interpret)

RELATIVE GROUNDS FOR REFUSAL.

- Except in rare circumstances of honest, concurrent use, a mark shall not be registered, if
  - it has identity with an earlier TM and similarity of goods or services; or
  - it has similarity to an earlier TM and the identity or similarity of the goods or services;
    and such identity or similarity is likely to cause confusion.
  - A TM has similarity/identity with an earlier well known TM even for dissimilar goods/services, if its use would take unfair advantage of, or be detrimental to, the distinctive character or repute of the earlier TM.
  - If its use is prevented by any law, particularly the law of passing off, protecting an unregistered TM

Similar, Identical, Deceptively similar, causes confusion

- Nature of the marks.
- Degree of resemblance (phonetic, visual as well as similarities in ideas).
- nature, character and purpose of goods
- class of purchasers
- trade channels
- Expressions and its legal effects in Trade marks
- Descriptive
- Disclaimer
- Common to Trade.

Descriptive expression

- ***When descriptive words are involved, some distinguishing element in***
- ***the use would be regarded as adequate. In Office Cleaning Service***
- ***s Ltd. v. Westminster Window & General Cleaners Ltd., the parties were engaged in the business of office cleaning. The plaintiffs traded under***
- ***the style of "Office Cleaning Services Ltd." and the defendants who***
- ***operated as "Westminster Office Cleaning The test where words are***
- ***descriptive has been laid down in Corpus Juris Secundum. Vol.87 in paras 34 and 35, at pages 271 as follows:***
- ***(a) "The true test in determining whether a particular name or phrase is descriptive is whether, as it is commonly used, it is reasonably***
- ***indicative and descriptive of the thing intended. In order to be***
- ***descriptive within the condemnation of the rule, it is sufficient if information is afforded as to the general nature or character of the article and it is not necessary that the words or marks used shall comprise a clear, complete and accurate description. The meaning which should be given is the impression and significance which are conveyed to the public. Whether words or marks claimed as trade marks are descriptive or whether they are suggestive or arbitrary and fanciful must be decided with respect to the articles to which they are applied and the mark must be considered as a whole".***

- ***When descriptive words are used, slight difference may be enough***

Effect of Disclaimer (Old and New law)

- The legal effect of disclaimer has been dealt in Registrar of Trade Marks v. Ashok Chandra Rakhit Ltd. 1955 Indlaw SC 88:
- The Hon'ble Supreme Court in an appeal from the judgment and order of the Calcutta High Court reversing the decision of the Registrar of Trade Marks whereby the Registrar had rectified the register by inserting a disclaimer in respect of a particular registered trade mark. This decision was relied upon to contend that despite the disclaimer in his case he is still entitled to claim the device of chef as forming part of his registered trade mark and the device of chef used by the respondent is an infringement of the appellant's proprietary rights. The argument cannot be accepted. Indeed as was observed by the Hon'ble Supreme Court in this decision **the real purpose of requiring a disclaimer, and for the matter of that the giving of a disclaimer, is to define the rights of the proprietor under the registration so as to minimize, even if it cannot wholly eliminate, the possibility of extravagant and unauthorized claims being made on the score of registration of the trade marks.**

Common to Trade

- *Trade marks may contain features that are common to the trade, over which no person has an exclusive right to use in connection with that trade.*
- *May consist of devices, or words, or get-up or a combination thereof.*
- *Matters common to the trade are of two kinds:*
  (1) those which are descriptive of the goods, and accordingly every trader has a right to use them; and
  (2) those which have no descriptive significance in relation to the particular goods but which by virtue of long use by different traders or due to other circumstances in the trade have become publici juris.
- *A mark which is common to the trade connected with particular goods cannot be considered adapted to distinguish those goods.*
- *Where a device is common to the trade, a special and particular representation of that device may be distinctive.*
- *Where a word is common to the trade, the word in combination with other words conveying a different idea may be considered distinctive.*
- *The Device of a star or the word 'Star' is common to the trade. A special representation of the 'Star' with embellishments or expressions like 'Seven Stars' or "Star of Hope" may be treated as distinctive.*

REMEDIES FOR INFRINGEMENT/ PASSING OFF OF TRADE MARK

- Two types of remedies are available to the owner of a trademark for unauthorized use of his or her mark or its imitation by a third party. These remedies are:
- an action for infringement in case of a registered
- trademark; and
- an action for passing off' in the case of an unregistered trademark
- While former is a statutory remedy, the latter is a common law remedy. In an action involving infringement or passing off, a court may grant relief of injunction and/or monetary compensation for damages for loss of business and/or confiscation/destruction of infringing labels and tags etc.
- Although registration of trademark is prima facie an evidence of validity of a trademark, yet the registration cannot upstage a prior consistent user of trademark, for the rule is **'priority in adoption prevails over priority in registration.**

How does one obtain trademark protection?
in other words

What do I do if someone is using my trademark? (How do I protect my trademark?)

- Common law trademark rights
  - Passing of action
- Registration (The Trade marks Act, 1999)
  - Infringement action

Remedies for Trademark Infringement

- Injunctive relief
  - Preliminary
  - Permanent
- Damages
  - Defendant's profits
  - Plaintiff's actual damages

Equitable Relief, Actual Damages, Punitive Damages, and Accounting for Profits

Equitable Relief

- **Injunctive relief is a crucial remedy for infringement of intellectual property rights, because this remedy protects the exclusivity of these rights, which no amount of money, by itself, can protect**
- **Equitable relief is always subject to the trial court's discretion**
- **In trademark cases, equitable relief is more readily available than damages and provides for a lower burden of proof, a shift in traditional rules of equity, because actual damages in trademark cases have a tendency to be too speculative**
- **Because of the presumption of irreparable injury in trademark cases flowing from a showing of infringement, courts have been receptive to changing the traditional preliminary injunction four-part test to a two-prong alternative test**

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Actual Damages

- **Every form of IP protection provides a damage remedy for past infringement or misappropriation**
- **Generally, recovery is based upon principles of causation and compensatory purpose, which both require that the wrongfully injured IP owner be restored back to his rightful position that s/he would have occupied had the wrong not been committed**
  - **Causation: Π must show s/he likely would have made the claimed sales, likely would have earned the claimed profit, but for the Δ's infringement, and, to recover actual damages (as opposed to an accounting) in trademark cases, Π must prove actual consumer confusion resulting in the diversion of sales**
  - **Compensation: all remedies in trademark cases are subject to principles of equity and broad discretion of the trial judge**

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HOW A G.I. IS DIFFERENT FROM A TRADE MARK?

- **A TRADE MARK IS A SIGN WHICH IS USED IN THE COURSE OF TRADE AND IT DISTINGUISHES GOODS OR SERVICES OF ONE ENTERPRISES FROM THOSE OF OTHER ENTERPRISES.**
- **WHEREAS A GEOGRAPHICAL INDICATION IS AN INDICATION USED TO IDENTIFY GOODS HAVING SPECIAL CHARACTERISTICS ORIGINATING FROM A DEFINITE GEOGRAPHICAL TERRITORY.**

- Trademarks are property that can be:
  - bought and sold (assigned);

    licensed, e.g.,
    - merchandising
    - endorsements and sponsorships,
    - co-branding promotions and contests.
    -

INTERNATIONAL APPROACH ON WELL KNOWN TRADE MARK

MALAYSIA:

"McCurry" was created based on the abbreviation of "Malaysia Chicken Curry" which is distinctly a Malaysian Concept. McCurry's contention was that McDonald has no exclusive right to the prefix "Mc." The opinion of the Court is that McDonald has proven all elements to show the existence of the act of passing off both under the traditional and extended form of passing off by McCurry. It is the Court's duty to protect the goodwill and reputation of McDonald which has been legally recognized worldwide. Therefore the claim of McDonald is allowed with costs.

In the Court of Appeal, the decision of lower *court is* **reversed on the ground:**

"In my judgement, a reasonable tribunal armed with the facts and evidence that was presented to the learned judge would have held for the defendant and against the plaintiff. This is because there was, in my respectfully, view, no proof of the tort of passing off in this case. And there was no judicial appreciation of the most important pieces of the evidence presented at trial". For the reasons already given, I would allow the appeal and reverse the findings of the learned judge.

United States of America;

THINKSHARP vs. SHARP

Applicant's mark Opponent's mark

"In as much as applicant's application contains no limitations with respect to channels of trade and classes of purchasers for the goods therein, we must presume that applicant's goods are sold in all the normal channels of trade to all of the usual purchasers. Thus, for purposes of our likelihood of confusion analysis, we must assume that both parties' goods (i.e., opposer's computers, videocassette players, and CD ROM players and applicant's educational computer software, videocassette tapes, and CD-ROMS) are sold in mass merchandisers and electronic stores and through the Internet to ordinary consumers. Nonetheless, this record does not contain evidence or testimony upon which we could base the conclusion those consumers would assume that computers, videocassette players and CD-ROM players, on the one hand, and educational computer software, videocassettes featuring educational programs, and CD-ROMS containing educational programs, on the other hand, are offered by the same entity. Simply because applicant's goods may be used in opposer's goods is not a sufficient basis to find that the goods are related. Opposes goods are hardware, while applicant's goods are bought for the content contained in the physical object. There is no evidence that these kinds of goods commonly emanate from the same sources

Although we have given opposer's mark the significant weight that must be accorded to famous marks, **in view of the cumulative differences in the marks SHARP and THINKSHARP and the parties' respective goods and services, confusion is not likely**

DECISION: *The opposition is dismissed*

JAPAN:

The Trade mark Examination Manual of the Japan Patent Office (JPO) leaves little doubt that this bar to registration reflects dilution principles:

• Well-known and famous trademarks, which have become widely known and have gained a high reputation, credit and popularity among consumers as a result of the company's long, hard efforts and a considerable amount of advertising costs, can be considered to possess sufficient capability to attract consumers and to have worthy property values themselves. •

The use of such well-known and famous trade marks by a third party may not necessarily cause confusion over the source of goods etc., but it may weaken the source-indicating function or harm the reputation of these well-known and famous trademarks. Therefore, it is necessary to sufficiently protect these trade marks from illicit use, bearing in mind such purposes.

The Trademark Examination Manual thus interprets Article 4-1(19) as incorporating both blurring and tarnishment concepts. Article 4-1(19) is designed to preclude registration of a trademark identical or similar to one that is "famous nationwide" because, even though the second registration "may not necessarily cause confusion of the source of goods, etc.," it "may weaken the source-indicating function or harm the reputation of the said famous trademark.

The Manual also **confirms that the bar to registration applies only where the applicant has "unfair intent",** *and not* **where the** *similarity of* **the marks arises** *"by chance". However, where the marks are very similar and the well-known mark is unusual (e.g., a coined word) the JPO trademark examiner is permitted to presume the existence of unfair intent.*

EUROPEAN COURT OF JUSTICE:

An English telemarketing company had registered the trade mark INTELMARK for its services. Intel Corporation proceeded against this registration, as the average consumer will, when taking notice of INTELMARK, have an association of the famous trade mark INTEL. That could reduce the impact of the well known trademark, to the detriment of the well known mark. Sufficient to give INTEL a stronger right, Intel Corporation argued. The ECJ looks at it from a different perspective. If for the average consumer the later mark calls the earlier mark with a reputation to mind, this fact is tantamount to the existence of a link between the both trademarks. Yet such link is not enough. There must be more at stake for the cancellation or an order to stop the use of a later mark; the user of the lookalike mark takes an unfair advantage of the use; the well-known mark dilutes; or the user of the later mark is detrimental to the repute of the well known mark.

Singapore:

In Novelty Pte Ltd. v. Amanresorts Ltd. [(2009) SGCA 13, March 31 2009), the Court of Appeal of Singapore has considered whether a modest cluster housing project in Singapore should be allowed to use the same name as an exclusive luxury resort in Bali. "The Court held that where a defendant applied on or after July 1 2004 to register a trade mark which is identical or similar to the plaintiff's well-known mark, the defendant's mark - regardless of whether the goods or services which it covers are similar or dissimilar to the goods or of whether the goods or services which it covers are similar or dissimilar to the goods or services covered by the plaintiff's mark - will be refused registration only if;

•use of the defendant's mark would indicate a connection between the goods or services covered by that trade mark and the plaintiff, and is likely to damage the interests of the plaintiff; or

• The plaintiff's trade mark is well known to the public at large in Singapore (and not merely "well known in Singapore"), and use of the defendant's mark would either "cause dilution in an unfair manner of the distinctive character of the [plaintiff's] trade mark".

•Canada

Land mark decisions from the Supreme Court of Canada involving famous marks: veuve Clicquot Ponsardin v. Boutiques Cliquot ltee, [2006] SCC 23, that revolved around the renowned VEUVE CL1CQUOT fine Chanpagne brand, and Mattel, Inc. v. 3894207 Canada Inc., 2006 [SCC] 22, over the name of the popular doll, BARBIE. Fame does not shift the burden ot proot; Liketinooa ot deception must be proved and will not be presumed.

•United Kingdom;

•The decision dt.18.6.2010 of a bench of CAN comprising of three members in the matter of Zurich Investment Company (Defendant Company) is worth a reading to understand how the Defendant Company, which was not an established entity, could successfully defend the objection of Zurich Insurance Company (the Applicant), which is an insurance major. The Bench held "that the applicant's objection fails because the Defendant Company has not adopted its name in bad faith and that the Applicant will not be prejudicially affected by the Defendant Company continuing to carry on its business in its name".

CONGRATULATIONS

Our Trust Chairman Mr. S. V. Veerramani, Managing Director M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai as been elected as president of Indian Drug Manufacturers Association, Mumbai. He is the first person from Tamil Nadu occupying this highest post.

We congratulate him for his elevation.

PRODUCTS FROM READY STOCKS

- ALBENDAZOLE
- AMBROXOL HCL
- AMISULPIRIDE
- AMLODIPINE BESYLATE
- AMPICILLIN TRIHYDRATE
- ATENOLOL
- BACLOFEN
- BALOFLOXACIN
- BERGAPTEN
- BETA CAROTENE (NATURAL)
- BROMELAIN
- BROMOHEXINE
- CALCITROL (FARMOSA)
- CAPSAICIN 95%
- CARISOPRODOL
- CEFIXIME
- CEFPODOXIME PROXETIL
- CEPHALEXIN
- CHLORPHENIRAMINE MALEATE
- CHONDROITIN SULPHATE
- CINNARIZINE
- CITRUS BIOFLAVONOIDS
- COENZYME Q10 (INDIAN)
- CYPROPHEPTADINE
- DIOSMIN
- DOMPERIDONE
- DOMPERIDONE MALEATE
- ESCITALOPRAM OXALATE
- ETHIONAMIDE
- EZETIMIBE
- FENBENDAZOLE
- FENUGREEK EXTRACT
- FERROUS ASCORBATE
- FERROUS BIS GLYCINATE
- FEXOFENADINE
- FLUCONAZOLE
- FLUNARIZINE HCL
- FLUOXETINE HCL
- FLUVOXAMINE MALEATE
- GLICLAZIDE
- GLUCOSAMINE SULPHATE
- GRAPE SEED EXTRACT
- GREEN TEA EXTRACT
- GUAIFENESIN
- HYDROCHLORTHIAZIDE
- IRON DEXTRAN
- IRON SUCROSE
- ISOTRETINOIN
- KETOPROFEN
- KETOROLAC TROMETHAMINE
- LOPERAMIDE
- LORATIDINE
- LOSARTAN POTASSIUM
- LUTEIN (NATURAL)
- LYCOPENE (NATURAL)
- METHOXSALEN
- METHYL SULPHONYL METHANE
- METOPROLOL SUCCINATE
- MINOXIDIL
- MIZOLASTIN
- OXACILLIN SODIUM
- OXETACAINE
- PANTOPRAZOLE
- PINE BARK EXTRACT
- PROTHIONAMIDE
- RABEPRAZOLE SODIUM
- RANITIDINE INJ. GRADE
- RESPERIDONE
- RUTIN NF (RUTOSIDE)
- S AMLODIPINE BESYLATE
- SILYMARINE 70% (INDIAN)
- SOY ISOFLAVONES 40%
- TERBINAFINE
- TRIOXSALEN
- TROXERUTIN
- UDCA
- ZINC ASCORBATE
- ZINC BIS GLYCINATE
- ZINC CARNOSINE

SPECIALITY OILS FOR COSMETICS & SOFTGEL

- GRAPE SEED OIL
- OLIVE OIL POMACE & VIRGIN
- SWEET ALMOND OIL
- WHEAT GERM OIL
- EVENING PRIMROSE OIL

Shubham
Pharmachem Pvt. Ltd.

207, Laxmi Plaza, Laxmi Industrial Estate, Building No.9, New Link Road, Andheri (W), Mumbai - 400 053, India.
Tel.: 26344608 / 09 / 10, 66914797 • Fax: 66923929 / 26318808
Email: shubham@shubham.co.in • Website: www.shubham.co.in

MULTIPARTICULATE TECHNOLOGY: FORMULATION AND PROCESSING CONSIDERATION

By

Dr. Jayesh Parmar

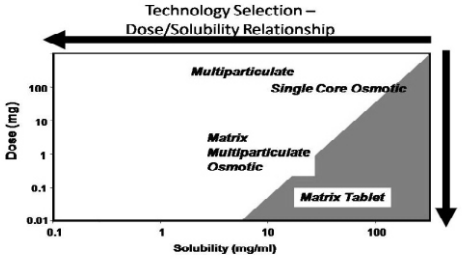
Formulation Technology Manager, Colorcon South Asia Manager, Goa

Lecture Delivered at 64th IPC Chennai, on 8th December 2012

Outline

- Selecting multiparticulate technology
- Multiparticulates
  - Types, advantages and challenges for oral delivery
- Multiparticulates formulation and processing
- Barrier Membrane coating
- How to modulate drug release ?
- Case study – Barrier membrane coated formulation
- Summary

Technology Selection – Dose/Solubility Relationship

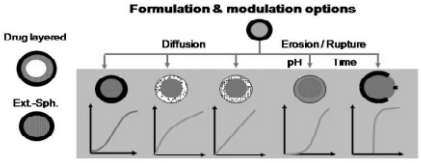


MP's are used in a wide range of dose-solubility combinations

Multiparticulates as Drug Delivery Systems

- Ease of administration
- Reduce variations in gastric emptying rates
  - reduced inter- and intra-subject variability
- Low concentration of bioactive agents locally
- Less susceptible to dose dumping
- Potential for multiple drugs / profiles

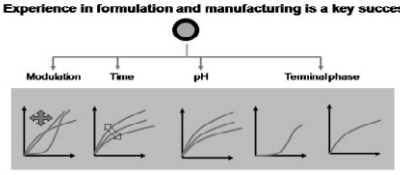
Formulation & modulation options



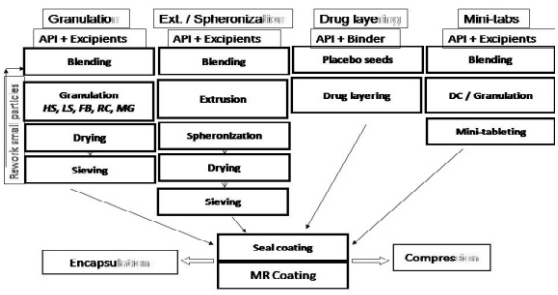
Challenges of MP Systems

- Drug release modulation
- Potential curing / stability issues
- pH effect on release profiles
- Complex process / large number of variables
- Terminal phase too slow or incomplete

Experience in formulation and manufacturing is a key success factor!



Multiparticulate Formulation and processing



Key Features of Substrates

	Drug-layered nonpareils	Extruded spheronized beads	Granules	Mini-tabs
Dose/Drug	Lower doses (<50 mg)	Higher doses (>50 mg)	Various	Various
Geometry	Isometric spheroids		Irregular shape, wide particle size distribution	Cylindrical/ convex
Manufacture	Slow	Multistage, complex	Slow	Conceptually simple, hidden complexity
Cost	Expensive	Expensive at scale	Least expensive	Relatively inexpensive
Process	Batch processing	Semi-continuous	Batch processing	Standard equipment
Scale-up	Challenging	Challenging	Challenging	Easier

MR Film Coating Applications

stable on storage and handling

uniform thickness

Criteria for good films and coatings

adhere to the substrate

coherent and free from flaws and cracks

Sakellariou and Rowe. Prog. Polym. Sci. 20, 889-942 (1995)

Ideally, it is inert, stable, flexible, reliable (functionality & quality), available & acceptable

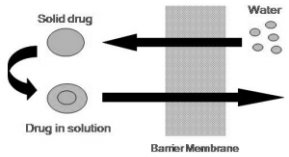
MR Film Coating Options

Polymer + Plasticizer + Anti-tack ± Release modifier +....

- pH dependent / Insoluble (permeable / semi-permeable) / soluble POLYMER
- Common DR polymers:
  - Poly Methacrylic acid ethylacrylates e.g. Eudragit/ Acryl-EZE
  - Cellulose acetate phthalate e.g. Aquacoat® CPD
  - Polyvinyl acetate phthalate (PVAP) e.g. Sureteric®
- Common ER polymers
  - Cellulose ethers e.g. ETHOCEL™, Surelease, Aquacoat ECD
  - Methacrylic acid esters e.g. Eudragit RS, RL, NM
  - Polyvinyl acetate e.g. Kollicoat SR
  - Cellulose esters e.g. Cellulose acetate (Opadry® CA)

- Organic coating vs. aqueous coating
- Polymer selection based on functional requirements and previous experience

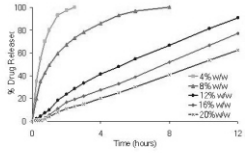
Barrier Membrane - Drug Release



Fick's 1st law of diffusion:

$$\frac{dM}{dT} = \frac{ADK\,\Delta C}{l}$$

A = surface area
D = diffusion coefficient
l = diffusion pathlength
C = conc. gradient
K = partition coefficient



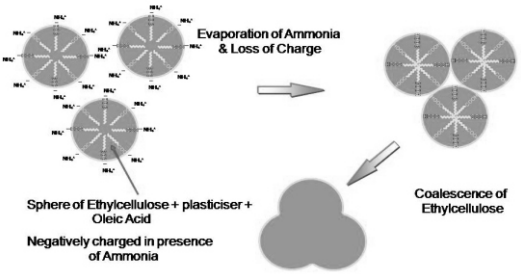
Ethylcellulose

- Ethylcellulose
  - Hydrophilic, but not water soluble polymer - organic solvent coating used
  - pH-independent drug release
  - Two aqueous latex dispersions are commercially available
- Aquacoat ECD (FMC)
  - 30% w/w solids
  - Stabilized with sodium lauryl sulfate and cetyl alcohol
  - Requires addition of plasticizers
- Surelease® (Colorcon)
  - 25% w/w solids
  - Stabilized by small particle size and ammonium oleate
  - Plasticized, ready to use system

Surelease - Product Descriptions

- **Aqueous Dispersion of Ethylcellulose**
  - proven performance with wide variety of drugs
  - no exposure to harmful solvents
- **Fully formulated**
  - ready plasticized for optimal coating performance
  - does not require any processing additives
- **Easy to use**
  - Variety of applications in phama and nutritional
- **Controlled permeability**
  - Ethylcellulose is insoluble in water
  - Permeable membrane, with diffusion controlled drug release
- **Good stability over wide pH ranges**
  - Low reactivity
  - Suitable for variety of drugs and applications

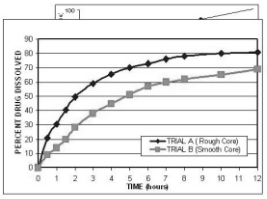
Surelease – Mechanism of Film Formation



Drug Release - Modulation

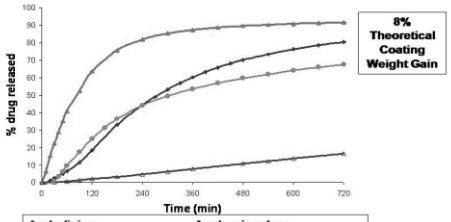
- **Starter core**
  - As surface area ↑, rate of release ↑
- **Film thickness**
  - As weight gain ↑, rate of release ↓
- **Polymer viscosity**
  - As viscosity ↑, strength of film ↑, but rate of release largely unaffected
- **Drug solubility**
  - As solubility ↑, rate of release ↑
- **Permeability of the film**
  - As Permeability of the film ↑, rate of release ↑
- **Choice of solvent**
  - Aqueous vs. organic solvent
  - Faster release from aq. than organic coated at equivalent thickness
- **Choice of plasticizer**
  - Water soluble vs. water insoluble
  - Faster if water soluble plasticizer is used

Drug Release : Pellet Size and Surface Condition



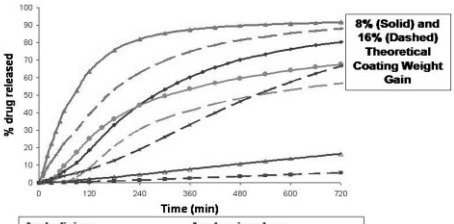
Ideal starter seed for MR coating:
"Narrow particle size distribution, hard, round & smooth surfaces"

Drug Release : Influence of EC Coating Level



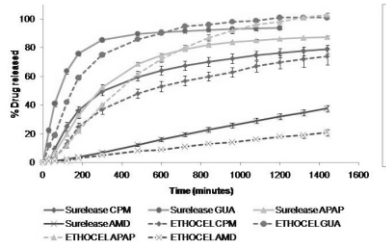
Amlodipine	Acetaminophen
Guaifenesin	Chlorpheniramine Maleate

Drug Release : Influence of EC Coating Level



Amlodipine	Acetaminophen
Guaifenesin	Chlorpheniramine Maleate

Drug Release : Solvent coated vs. Surelease coating



Substrate: Drug layered Suglets

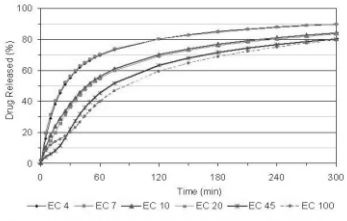
Organic: ETHOCEL Std10 Prem
Plasticizer: DBS 10% w.r.t. EC
Solvent: IPA: water (90:10)

ETHOCEL weight Gain: 10%
Surelease weight gain: 8%

Pam-Glatt GPCG-1

Drug release rate : GUA > APAP > CPM > AMD regardless of coating solvent

Drug Release : Effect of Mol. Weight for Organic Ethylcellulose



Polymer:
Ethylcellulose 4, 7, 10, 20, 45, 100cP

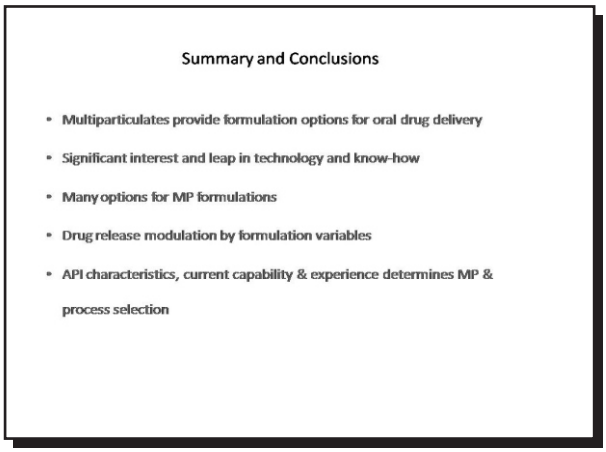
Plasticizer:
Dibutyl sebacate10% (w/w)

Solvent:
Ethanol, 190 proof
Solids Content: 5% (w/v)
Weight Gain: 13%
Mini-Glatt (Wurster)

Substrate:
Nonpareil beads 30-35 mesh
Diphenhydramine HCl (very soluble, 1:1)

Coppens, K.A., Dasbach, T.P., Frauchiger, L., 31st Annual Meeting of the CRS, 2004.

Slight decrease in a very soluble drug release rate with an increase in polymer MW



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This issue of Pharma Web is also available online at the Trust website www.pictrust.com

NOTIFICATIONS

REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 30th August, 2013

G.S.R. 589(E).—The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Fourth Amendment) Rules, 2013.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, after Serial Number 35 and the entries relating thereto, the following shall be inserted, namely:-

Class of Drugs	Extent and Conditions of Exemption
"36. Zinc sulphate tablets and oral solutions having 10 mg and 20 mg of elemental zinc.	The provisions of Chapter IV of the Act and Rules thereunder which require them to be covered by a sale licence, subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.".

[F. No. X-11014/5/2012-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot Note : The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 72(E), dated the 8th February, 2013.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th August, 2013

G.S.R. 588(E) - Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), without consulting the Drugs Technical Advisory Board vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R 228(E), dated the 20th March 2012, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 20th March 2012, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the Gazette in which the said notification was published were made available to the public on the 20th March 2012;

And whereas, the Drugs Technical Advisory Board has been consulted in the matter,

And whereas, objections and suggestions received in respect of the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Fourth Amendment) Rules, 2013

(2) They shall come into force after six months of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules)

(I) in rule 65

(a) in condition (3), in clause (1)

(A) in sub-clause (f) and in item (ii) of the third proviso to sub-clause (g), for the words and letter 'Schedule H' the words and letters "Schedule H and Schedule H1" shall respectively be substituted;

(B) after clause (g) and the provisos thereof, the following shall be inserted, namely:-

"(h) the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

(b) in condition (9), in clauses (a) and (b), for the words and letter 'Schedule H' the words and letters "Schedule H and Schedule H1" shall respectively be substituted;

(h) in condition (11), for the words and letter 'Schedule H' the words and letters "Schedule H and Schedule H1" shall be substituted;

(d) in condition (11A), for the words and letter 'Schedule H' the words and letters "Schedule H and Schedule H1" shall be substituted;

(ii) in rule 97, in sub rule (1), after clause (d) the following shall be inserted, namely:-

(e) if it contains a drug substance specified in Schedule H1, the drug formulation shall be labeled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labeled with the following words in a box with a red border:

"SCHEDULE H1 DRUG - WARNING:

It is dangerous to take this preparation except in accordance with the medical advice.

Not to be sold by retail without the prescription of a Registered Medical Practitioner"

3. In the said rules, in Schedule H, the following entries shall be omitted, namely:-

1. Alprazolam
2. Cefdinir
3. Cefepime Hydrochloride
4. Cefetamet Pivoxil
5. Cefpirome
6. Cefpodoxime Poxetil
7. Ceftazidime Pentahydrate
8. Ceftizoxime Sodium
9. Chlordiazepoxide
10. Clofazimine
11. Codeine
12. Diazepam
13. Diphenoxylate and its salts
14. Ethambutol Hydrochloride
15. Ethionamide
16. Levofloxacin
17. Meropenam
18. Midazolam
19. Moxifloxacin
20. Nitrazepam
21. Pentazocine
22. Pyrazinamide
23. Sparfloxacin
24. Thiacetazone
25. Tramadol Hydrochloride
26. Zolpidem

4. In the said rules, after Schedule H, the following Schedule shall be inserted, namely:

"Schedule H1

(See rules 65 and 97)

1. Alprazolam
2. Balofloxacin
3. Buprenorphine
4. Capreomycin
5. Cefdinir
6. Cefditoren
7. Cefepime
8. Cefetamet
9. Cefixime
10. Cefoperazone
11. Cefotaxime
12. Cefpirome
13. Cefpodoxime
14. Ceftazidime
15. Ceftibuten
16. Ceftizoxime
17. Ceftriaxone
18. Chlordiazepoxide
19. Clofazimine
20. Codeine
21. Cycloserine
22. Diazepam

23.Diphenoxylate
24.Doripenem
25.Ertapenem
26.Ethambutol Hydrochloride
27.Ethionamide
28.Feropenem
29.Gemifloxacin
30.imipenem
31.Isoniazid
32.Levofloxacin
33.Meropenem
34.Midazolam
35.Moxifloxacin
36.Nitrazepam
37.Pentazocine
38.Prulifloxacin
39.Pyrazinamide
40.Rifabutin
41.Rifampicin
42.Sodium Para-aminosalicylate
43.Sparfloxacin
44.Thiacetazone
45.Tramadol
46.Zolpidem

Note:- Preparations containing the above drug substances and their salts excluding those intended for topical or external use (except ophthalmic and ear or nose preparations) containing above substances are also covered by this Schedule".

[F.No.X-11014/6/2010 -DFQC]

ARUN K PANDA, Jt Secy

Foot note:- The principal rules were published in the Official Gazette vide notification No. F-28-10/45-H(1), dated 21st December , 1945 and last amended vide notification number **G.S.R. 72(E), dated the 8th February, 2013**

CONGRATULATIONS

Mr. K. Kaliyannan, Joint Director of Drugs Control, (Retd,) Govt. of Tamilnadu has been elected as President of Erode District Chemists and Druggists Association again for the year 2013 to 2016. He has been nominated as a member of Erode District Consumer Protection Council by Govt. of Tamilnadu for the period of three years. He is also Ex. EC member of Tamilnadu Pharmacy Council and an active EC member of Drugs Control Department Retired Officers Association of Tamilnadu.

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
PUBLISHED BY AUTHORITY

No. 534] NEW DELHI, THURSDAY, OCTOBER 24, 2013/KARTIKA 2, 1935

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th October, 2013

G.S.R.702 (E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the principal rules), which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, are hereby published for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules shall be taken into consideration after the expiry of a period of forty-five days from the date on which the copies of the Official Gazette in which this notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Secretary (Health), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

The objections or suggestions, which may be received from any person with respect to the said draft rules before the expiry of the period specified above, shall be considered by the Central Government.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (5th Amendment) Rules, 2013.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In rule 2 of the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the principal rules), after the clause (ea) the following clause shall be inserted, namely:-

"(eb) "Phytopharmaceutical drug" includes processed or unprocessed standardised materials derived from plants or parts thereof or combination of parts of plants, extracts or fractions thereof in a dosage form for internal or external use of human beings or animals and intended to be used

for diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, but does not include administration by parenteral route;".

3. In rule 122-A of the principal rules,-

(i) in sub-rule (1), in clause (b), in the second proviso, for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted;

(ii) in sub-rule (2), for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted;

4. In rule 122-B of the principal rules,-

(i) in sub-rule (1), in clause (b), in the second proviso, for the words, figures and letters "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted;

(ii) in sub-rule (2), for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted;

5. In rule 122-E of the principal rules, in clause (a), after the words "bulk drugs substance," the words "or phytopharmaceutical drug" shall be inserted.

6. In Schedule Y of the principal rules, after APPENDIX I-A, the following Appendix shall be inserted, namely:-

"APPENDIX I-B

DATA TO BE SUBMITTED ALONG WITH APPLICATION TO CONDUCT CLINICAL TRIAL OR IMPORT OR MANUFACTURE OF A HYTOPHARMACEUTICAL DRUG IN THE COUNTRY

PART - I

1. **Basic Information:**

1.1. A brief description or summary of the Phytopharmaceutical drug including the name of plant (including vernacular or Sanskrit name, wherever applicable) formulation and route of administration, dosages, therapeutic class for which it is indicated and the claims to be made for the Phytopharmaceutical product.

1.2. Relevant published literature including information on plants or products or Phytopharmaceutical, as a traditional medicine or as an ethno medicine, and also provide reference to books and other documents, regarding composition, process prescribed, dose or method of usage, proportion of the active ingredients in such traditional preparations per dose or per day's consumption and uses.

1.3. Information on any contraindications, side effects mentioned in traditional medicine or ethno medicine literature or reports on current usage of the formulations.

1.4. Published scientific reports in respect of safety and pharmacological studies relevant for the Phytopharmaceutical drug intended to be marketed,-

(a) where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and

(b) where process or usage is different from that known in traditional medicine or ethno medicine.

1.5 Present usage of the Phytopharmaceutical drug – provide details giving the name of the products, manufacturer(s), quantum sold, extent of exposure of human population and number of years the product or products have been sold to establish history of usage.

2. **Human or Clinical Pharmacology information :**

2.1. Published scientific reports in respect of pharmacological studies including human studies or clinical studies or epidemiological studies, relevant for the Phytopharmaceutical drug intended to be marketed,-

(a) where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and

(b) where process or usage is different from that known in traditional medicine or ethno medicine.

2.2. Information on any contraindication, side effects mentioned or reported in any of these studies. information on side effects and adverse reactions reported during current usage of the Phytopharmaceutical(s) in the last three years. if the Phytopharmaceutical drug has the same process or the same usage.

2.3. Pharmacodynamic information (If available)

2.4. Monographs, if any, published on the plant or product or extract or Phytopharmaceutical.

[attach copies of all publications, along with English translation].

PART – II

Data generated by applicant

3. **Pharmacognostic description**

3.1. Taxonomical identity of the plant(s) used as a source of the Phytopharmaceutical, and the botanical identity giving the genus, species and family, followed by the authority citation (taxonomist's name who named the species), the variety or the cultivar (if any) also needs to be mentioned.

3.2. Morphological and anatomical description giving diagnostic features and a photograph of the plant and/or plant part for further confirmation of identity. (Furnish certificate of confirmation of botanical identity by a qualified taxonomist).

3.3. Natural habitat and geographical distribution of the plant(s).

3.4. Source(s) of the plant(s) including its geographical location and whether it is cultivated or harvested from the wild.

3.5. Season or time of collection.

3.6. A statement indicating whether the species is any of the following:

(a) Determined to be endangered or threatened under the Endangered Species Act or the Convention on International Trade in Endangered species (CITES) of wild Fauna and Flora.

(b) Entitled to special protection under the Biodiversity Act.

(c) Any known genotypic, chemotypic and ecotypic variability of species.

3.7. A list of grower(s) and/or suppliers (including names and addresses) and information on the following items should be provided for each grower or supplier, if available or identified already, including information of primary processing, namely:-

(a) harvest location;

(b) growth conditions;

(c) stage of plant growth at harvest;

(d) harvesting time;

(e) collection, washing, drying, garbling and preservation procedures;

(f) handling transportation and storage conditions.

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3.8. Quality specifications, namely:-

(a) foreign matter;

(b) moisture content;

(c) volatile matter (if any);

(d) total ash;

(e) acid insoluble ash;

(f) extractive value;

(g) pesticide residue;

(h) heavy metal contamination;

(i) microbial load;

(j) adventitious toxins (e.g. aflotoxins, if any);

(k) chromatographic finger print profile with phytochemical reference maker/(s);

(l) assay for active constituent/(s) or characteristic maker/(s) if active constituents are not known.

3.9. An undertaking to supply specimen sample of plant duly labeled and photocopy of the identity confirmation certificate issued by qualified taxonomist along with drawings or photographs of the diagnostic morphological and histological features of the botanical raw material used for the confirmation of authenticity.

3.10. Chromatographic fingerprint of a sample as per test method given under quality control of the Phytopharmaceutical (photo documentation).

4. **Processing of extract or Phytopharmaceutical (if used as an extract)**

4.1. Quality specifications and test methods for the starting material.

4.2. Details of the steps used in processing of the Phytopharmaceutical, with special reference to the changes from the traditional medicine or ethno medicine processes, including any enrichment steps.

4.3. Details of solvents used, extractive values, solvent residue tests or limits, physico-chemical tests, microbial loads, heavy metal contaminants, chromatographic finger print profile with phytochemical reference markers, assay for active constituents or characteristic markers, if active constituents are not known.

4.4. Data on the active Phytopharmaceutical establishing the natural window of constituents (marker compounds) reflecting geographical and seasonal changes in a year, wherever applicable.

4.5. Information on any excipients (diluents or builders or stabilizers or preservatives used, if any) and their proportions.

4.6. Details of packaging of the extract or Phytopharmaceutical, storage conditions and labeling.

5. **Formulation of Phytopharmaceutical drug applied for :**

5.1. Details of the composition, proportion of extract or Phytopharmaceutical per unit dose, name and proportions of all excipients, stabilizers and any other agents used, packaging materials.

5.2. Test(s) for the identification for the Phytopharmaceutical.

5.3. Quality specifications for actives and inactive Phytopharmaceutical, chromatographic finger print profile with phytochemical reference maker(s) and assay for active constituent(s) or characteristic maker(s), if active constituents are not known.

6. **Manufacturing process of formulation :**

6.1. The outline of the method of manufacture of the dosage form, along with environmental controls, in-process quality control tests and limits for acceptance.

6.2. Details of all packaging materials used, packing steps and description of the final packs.

6.3. Finished products, quality specifications, including tests specific for the dosage form, quality and chromatographic finger print profile with phytochemical reference marker(s) and assay for active constituent(s) or characteristic marker(s), if active constituents are not known.

7. **Stability data:**

7.1. Stability data of the extract or Phytopharmaceutical as described at 4.0 above, stored at room temperature and at 40deg +/- 2 deg C / 75%RH +/- 5 %RH for 0, 1, 2, 3 and 6 months.

7.2. Stability data of the Phytopharmaceutical(s) dosage form or formulation stored at room temperature and at 40 deg+/- 2 deg C / 75%RH +/- 5 %RH for 0, 1, 2, 3 and 6 months, in the pack intended for marketing.

8. **Safety and pharmacological information:**

8.1. In case the Phytopharmaceutical's processing is different from the way it is done in traditional medicine or ethno medicine, provide comparative chemical and chromatographic profile, and spectroscopic information where ever applicable, to demonstrate the similarities and dissimilarities between the two.

8.2. **Animal toxicity and safety data :**

(a) 28 to 90 days repeat dose oral toxicity on two species of animals of which one should be non rodent as per Schedule Y;

(b) In-vitro Genotoxicity data (Ame's test and Chromosomal aberration test as per Schedule Y);

(c) Dermal toxicity tests for topical use products;

(d) Teratogenicity study (only if Phytopharmaceutical (s) is intended for usage during pregnancy).

9. **Human Studies :**

9.1. For all Phytopharmaceutical- Data from Phase I (to determine Maximum Tolerated Dose and associated toxicities) and the protocols shall be submitted prior to performing the studies.

9.2. Data of results of dose finding studies performed and the protocols shall be submitted prior to performing the studies.

Provided that in the case of Phytopharmaceutical already marketed for more than five years or there is adequate published evidence regarding the safety of the Phytopharmaceutical drug the studies may be abbreviated, modified or relaxed.

10. **Proof of concept or confirmatory clinical trials :**

10.1. Submit protocols for approval for any specific or special safety and efficacy study proposed specific to the Phytopharmaceutical product.

10.2. Submit proposed protocol for approval for human clinical studies appropriate to generate or validate safety and efficacy data for the Phytopharmaceutical dosage form or product.

10.3. Submit information on how the quality of the formulation would be maintained during the above studies.

11. **Regulatory status:**

11.1. Status of the Phytopharmaceutical marketed in any country under any category like functional food or dietary supplement or as traditional medicine or as an approved drug.

12. **Marketing Information :**

12.1. Details of package insert or patient information sheet of the Phytopharmaceutical to be marketed.

12.2. Draft of the text for label and carton.

13. **Post Marketing Surveillance [PMS] :**

13.1. The applicant shall furnish periodic safety update reports every six months for the first two years and after approval the drug is granted.

13.2. For subsequent two years the periodic safety update reports need to be submitted annually.

14. Any other relevant data which the applicant considers that it will help in scientific evaluation of the application.".

[F.NO. X 11014/2/2012-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot note : The principal rules were published in the Gazette *vide* notification No. F. 28-10/45-H (1), dated the 21st December 1945 and last amended vide notification number G.S.R. 588 (E), dated the 30th August, 2013.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th October, 2013

G.S.R. 703(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government, proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty-five days from the date on which copies of the Gazette of India in which this notification is published, are made available to the public;

Any person interested in making any objection or suggestion on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (6th Amendment) Rules, 2013.

(2) They shall come into force on the date of their final publication in the Official Gazette

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 76, in sub-rule (1),—

(a) in the second proviso, for the words "Provided that", the words "Provided further that" shall be substituted;

(b) for the third proviso, the following proviso shall be substituted, namely:—

"Provided also that for medical devices specified in Schedule C, the whole time employee under whose supervision the manufacture or testing is conducted shall be—

(i) a graduate in Pharmacy or Engineering (in appropriate branch) from a University recognised by the Central Government for such purposes and has had at least eighteen months practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(ii) a graduate in science, from a University recognised by the Central Government for such purposes. with Physics or Chemistry or Microbiology as one of the subject and has had at least three years practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(iii) a diploma in Pharmacy or Engineering (in appropriate branch) from a Board or Institute recognised by the Central Government or the State Government for such purposes and has had at least four years practical experience in the manufacturing or testing of devices to which this licence applies after his diploma; or

(iv) having a foreign qualification, the quality and content of training of which are comparable with those prescribed in clause (i), clause (ii) and clause (iii) above, and is permitted to work as competent technical staff under this rule by the Central Government.".

3. In the said rules, for rule 109-A, the following rule shall be substituted, namely:—

'*109-A. Labelling of medical devices.*—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 shelf pack of the medical device and on every other outer covering in which the medical device is packed, namely:—

(a) proper name of the medical device;

(b) details necessary for the user to identify the device and its use;

(c) name of the manufacturer and address of the manufacturing premises where the device has been manufactured;

(d) correct statement of the net quantity, in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package shall be expressed in metric system; and

(e) date of manufacture and date of expiry:

Provided if the device is made up of stable materials such as stainless steel or titanium, date of expiry may not be necessary;

(f) to provide, wherever required, an indication that the device contains medicinal or biological substance;

(g) to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";

(h) to indicate, wherever required, any special storage or handling conditions applicable to the device;

(i) to indicate, if the device is supplied as a sterile product, its sterile state and the sterilization method;

(j) to give, if considered relevant, warnings or precautions for the attention of the user of the medical device;

(k) to label the device, if the device is intended for single use;

(l) to overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;

(m) to overprint on the label of the device, the words "Physician's Sample—Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample;

(n) to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M. L";

(o) to provide on the label, in case of imported devices, with the approval of the licensing authority mentioned in Rule 21, the import licence number, name and address of the importer and address of the actual manufacturing premises, date of manufacture, (if not already printed at the time of import):

Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for standardisation (ISO) may be used in lieu of text and the device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, for example, for a newly introduced symbol; an explanation shall be provided in the instructions for use.'.

4. In the said rules, after rule 109-A as so substituted, the following rules shall be inserted, namely :—

'109B. Exemption of certain labelling requirements for medical devices for export from India.— Labels on packages or container of devices for export shall be adopted to meet specific requirements of the law of the country to which the device is to be exported, but the following particulars shall appear in conspicuous manner on the label of the shelf pack of the medical device in which the device is packed and every other outer covering in which the container is packed :—

(a) name of the Device;

(b) distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B.No.";

(c) date of expiry, if any;

(d) name and address of the manufacturer and address of actual premises where the device has been manufactured

(e) manufacturing Licence No. preceded by the letters "M.L. No." or "Manufacturing Licence No.";

(f) internationally recognised symbols in lieu of text, wherever required:

Provided that where a device is required by the consignee not to be labelled with the name and address of the manufacturer, the label on the packages or container shall bear a code number as approved by the licensing authority. The code number shall bear the name of the State or Union Territory, in abbreviation, followed by the word "Device" and "manufacturing licence number":

Provided further that where a device is required by the consignee not to be labelled with the code number also, the label on the packages or container shall bear a special code number, as requested by the consignee, and approved by the licensing authority under rule 21.

109C. Shelf life of the medical devices.—Shelf life of the medical devices shall not exceed sixty months from the date of manufacture:

Provided that this period may be extended by the licensing authority, in respect of any specified medical device, if satisfactory evidence is produced by the manufacturer to justify such an extension.'.

5. In the said rules, in Schedule D, after item number 6 and the entries relating thereto, the following item number and entries shall be inserted, namely :—

Class of Drugs	Extent and Conditions of Exemptions
"7. Custom Made Devices	All provisions of Chapter III of the Act and the rules made thereunder, subject to the condition that the device is specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design characteristics and is intended for the sole use of a particular patient. The label should bear the word "Custom made device". *Explanation.*—Mass produced devices which only need adoption to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be Custom made devices."

6. In the said rules, in Schedule K, after item number 34 and the entries relating thereto, the following item number and entries shall be inserted, namely :—

Class of Drugs	Extent and Condition of Exemptions
"35. Custom made devices	All provisions of Chapter IV of the Act and the rules made thereunder, subject to the condition that the device being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design characteristics and is intended for the sole use of a particular patient .The label should bear the word "Custom made device". *Explanation.*— Mass produced devices which only need adoption to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be Custom made devices".

7. In the said rules, for Schedule R-1, the following Schedule shall be substituted, namely :-

"Schedule R-1

(See rules 109A, 109B, 109C and 125A)

The medical devices shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards (BIS). If there are no BIS standards then it shall conform to the International Standards, like International Organisation for Standardisation (ISO), or other International Pharmacopeia Standards and such other standards as may be prescribed. In case national or international standards are not available, the device shall conform to the manufacturer's validated standards.".

[F. No. X. 11014/ 3/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot Note : The principal rules were published in the Gazette of India *vide* Notification number F. 28-10/45-H (1), dated 21st December, 1945 and last amended *vide* notification number G.S.R. 588(E), dated 30th August, 2013.

REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
PUBLISHED BY AUTHORITY

No. 553] NEW DELHI, THURSDAY, NOVEMBER 7, 2013/KARTIKA 16, 1935

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 7th November, 2013

G.S.R. 724(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by Section 12 read with Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 43(E), dated the 24th January, 2013, in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), dated the 24th January, 2013, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 24th January, 2013;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under Section 12 read with Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :—

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2013.
   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the principal rules), in rule 69A, in sub-rule (1), for the *Explanation, the* following *Explanation* shall be substituted, namely :—
   "*Explanation.*-For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 25.".

3. In rule 75A of the principal rules, in sub-rule (1), for the *Explanation*, the following *Explanation* shall be substituted, namely :—
   "*Explanation.*-For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 28.".

4. In rule 122E of the principal rules, in clause (c), in the *Explanation*, in item (ii), the words "or its inclusion in the Indian Pharmacopoeia, whichever is earlier" shall be omitted;

5. In Schedule D of the principal rules, against serial number 1, under the column heading 'Extent and conditions of exemption', after the words "or is of commercial quality.", the words, "Further, permission from licensing authority as defined in clause (b) of rule 21 has to be obtained for import of the substance for non-medicinal use without registration and import licence." shall be inserted.

6. In Schedule H of the principal rules, the serial number 269 and the entries relating thereto shall be omitted.

7. In Schedule S of the principal rules, after serial number 29 and the entries relating thereto, the following serial number and entry shall be inserted, namely :—
   "30. Sindoor IS:14649:1999.".

8. In Schedule X of the principal rules, after the item 'Glutethimide', the following item shall be inserted, namely :
   "Ketamine hydrochloride".

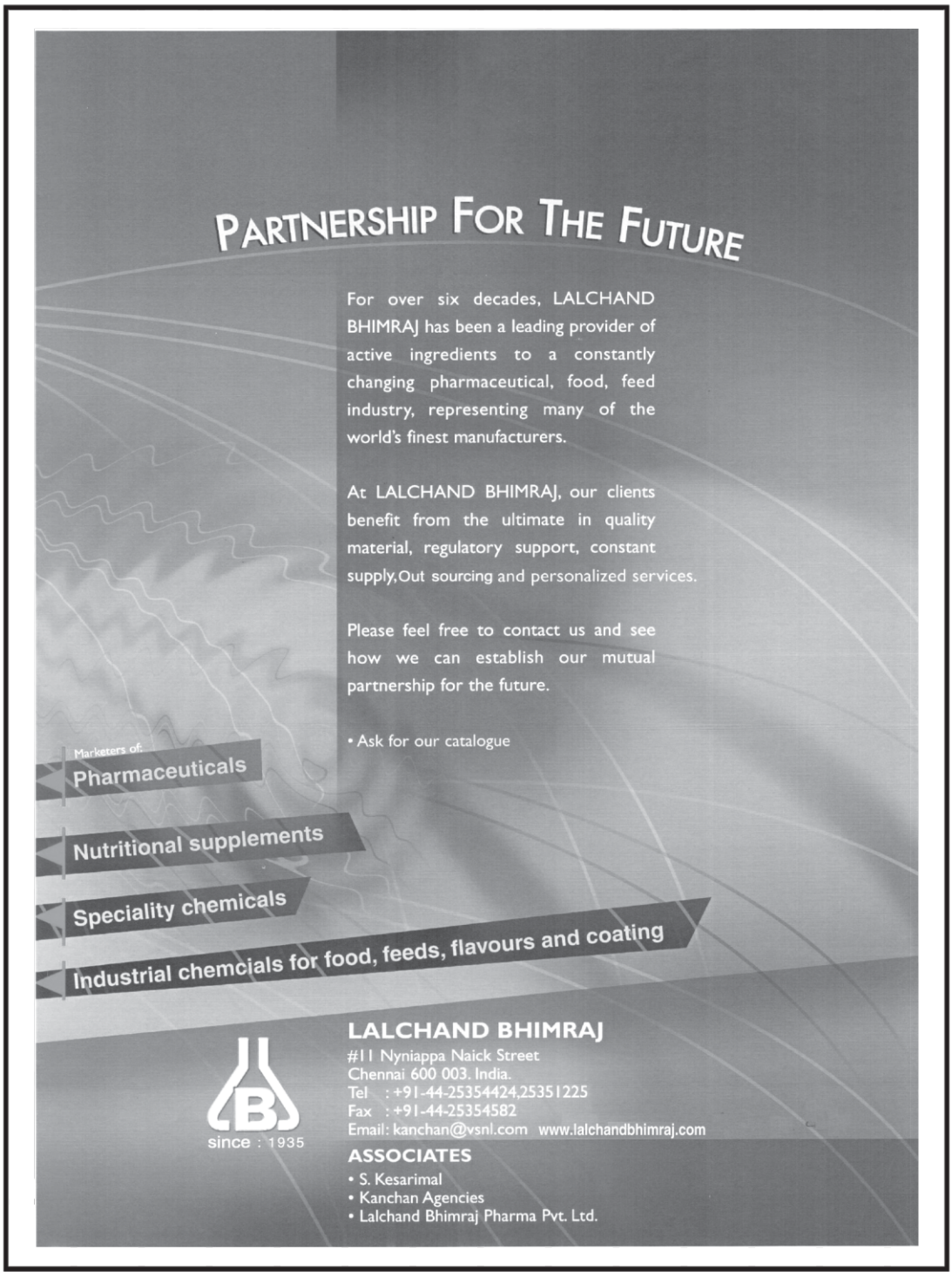
[F. No.-X-11014/10/2011-DFQC]

ARUN K. PANDA, Jt. Secy.

Parliamentary Standing Committee Turn Down The CDA

The constitution of a Central Drugs Authority and its composition. Neither the Mashelkar Committee Report nor the Committee on Health and Family Welfare in its 30th Report on the Drugs and Cosmetics (Amendment) Bill, 2007 presented to the House on the 21st October, 2008 recommended for constitution of a Central Drugs Authority (CDA) as proposed in the Bill. Instead, both the Reports recommended for strengthening of the existing Drugs Regulatory Body i.e. CDSCO and a strong Central Drug Administration. The proposed CDA is studded with bureaucratic heads of seven Central Ministries and four Secretary and Additional Secretary/ Joint Secretary level bureaucrats as ex-officio members of the CDA with Health Secretary as its Chairperson. The proposed CDA and its composition is unprecedented as no other Regulatory Body in the country or outside the country has such composition and it is not acceptable to the Committee. As regards the Central Drugs Administration (CDA), the Committee feels that there is a need for effective discharge of the enforcement activities and it requires a strong, professionally managed administration as enforcement activities require actions against unscrupulous manufacturing companies and coordination with various state regulatory authorities. The Central Drug Administration should be headed by a Chief Drug Controller General of India of the rank of Secretary/ Special Secretary having requisite technical and professional qualifications and expertise/experience pertaining to various aspects of drugs, medical devices and clinical trials. Besides, there should be three separate divisions-one each for the drugs, medical devices and conduct of clinical trials headed by their respective Drugs/ Medical Devices/ Clinical Trials Controllers having requisite technical and professional qualifications and expertise/ experience in their respective fields and duly supported by well-trained technical/ professional officers and staff. The proposed administration should be given adequate autonomy to discharge its functions enumerated under the Act. The Committee therefore, recommends that the words "Central Drugs Authority" may be replaced by "Central Drugs Administration". It is proposed that Central Drugs Administration will be answerable to the Ministry of Health and Family Welfare. The Chief Controller General of India will be selected through Search-cum-selection Committee headed by the Cabinet Secretary and a process similar to appointment of Secretary, Department of Biotechnology may be considered. Accordingly, Section 4A to 4I and 4K to 4O should be amended suitably. The Committee further recommends that there should be a provision for review of functioning of CDA by a panel of independent experts in the act itself. The Committee also recommends that consequential changes in the Act may also be made.

Source: *Extracts from 79th report on The Drugs and Cosmetics (Amendment) Bill*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List of NLEM drugs with Ceiling Prices

S. No	S.O.No	Date	Name of the Schedule Formulation	Strength	Unit	Ceiling Price (Rs.)
1	2830(E)	9/20/2013	Allopurinol Tablets	100mg	100mg	2.09
2	2831(E)	9/20/2013	Dexchlorpheniramine Maleate Syrup	0.5mg/5ml	1 ml	0.3
3	2832(E)	9/20/2013	Promethazine Tablet	10mg	1 Tablet	0.93
4	2833(E)	9/20/2013	Phenobarbitone Syrup	20mg/5ml	1 ml	0.41
5	2834(E)	9/20/2013	Piperazine Solution	750mg/5ml	1 ml	0.28
6	2835(E)	9/20/2013	Dapsone Tablet	50mg	1 Tablet	0.2
7	2836(E)	9/20/2013	Dapsone Tablet	100mg	1 Tablet	0.22
8	2837(E)	9/20/2013	Ethambutol Tablet	200mg	1 Tablet	0.97
9	2838(E)	9/20/2013	Isoniazid Tablet	100mg	1 Tablet	0.72
10	2839(E)	9/20/2013	Acyclovir Suspension	400mg/5ml	1 ml	1.32
11	2840(E)	9/20/2013	Didanosine Tablet	250mg	1 Tablet	23.93
12	2841(E)	9/20/2013	Stavudine Capsule	30mg	1 Capsule	2.75
13	2842(E)	9/20/2013	Stavudine Capsule	40mg	1 Capsule	3.12
14	2843(E)	9/20/2013	Diltiazem Injection	5mg/ml	1 ml	3.02
15	2844(E)	9/20/2013	Nifedipine Sustained Release Capsule	10mg	1 Capsule	1.67
16	2845(E)	9/20/2013	Nifedipine Sustained Release Capsule	20mg	1 Capsule	2.19
17	2846(E)	9/20/2013	Beclomethasone Dipropionate Inhalation	50mcg/Dose	1 Inhaler	169.37
18	2847(E)	9/20/2013	Hydrocortisone Sodium Succinate Injection	200mg	1 ml	71.45
19	2848(E)	9/20/2013	Ipratropium Bromide Inhalation	20mcg/MT Dose	1 MT Dose	0.68
20	2849(E)	9/20/2013	Fluconazole Capsule	100mg	1 Capsule	23.81
21	2850(E)	9/20/2013	Sevoflurane Inhalation	--	1 ml	27.99
22	2851(E)	9/20/2013	Bupivacaine Hydrochloride Injection	0.25%	1 ml	2.31
23	2852(E)	9/20/2013	Bupivacaine Hydrochloride Injection	0.50%	1 ml	3.49
24	2853(E)	9/20/2013	Bupivacaine Hydrochloride Injection	0.5% to be mixed with 7.5% Glucose Solution	1 ml	5.73
25	2854(E)	9/20/2013	Lignocaine Hydrochloride Topical Forms	2-5%	1 ml / gm	1.18
26	2855(E)	9/20/2013	Lignocaine Hydrochloride + Adrenaline Injection	2% + Adrenaline 1:200,000	1 ml	0.57

27	2856(E)	9/20/2013	Morphine Sulphate Injection	10mg/ml	1 ml	21.52
28	2857(E)	9/20/2013	Morphine Sulphate Tablet	10mg	1 Tablet	5.04
29	2858(E)	9/20/2013	Heparin Sodium Injection	5000 IU/ml	1 ml	40.62
30	2859(E)	9/20/2013	Calamine Lotion	--	1 ml / gm	0.97
31	2860(E)	9/20/2013	Glutaraldehyde Solution	2%	1 ml	0.08
32	2861(E)	9/20/2013	Sulphacetamide Sodium Drop	10%	1 ml	2.85
33	2862(E)	9/20/2013	Pilocarpine Drop	2%	1 ml	9.9
34	2863(E)	9/20/2013	Ringer Lactate Injection	As per IP	1 ml	0.1
35	2864(E)	9/20/2013	Sodium Bicarbonate Injection	As per IP	1 ml	1.27
36	2865(E)	9/20/2013	Water for Injection	5ml	1 Ampoule	3.45
37	2866(E)	9/20/2013	Water for Injection	10ml	1 Ampoule	4.76
38	2867(E)	9/20/2013	Calcium Carbonate Tablet	250mg	1 Tablet	1.68
39	2868(E)	9/20/2013	Calcium Gluconate Injection	100mg in 10ml Ampoule	10ml Ampoule	9.95
40	2869(E)	9/20/2013	Diclofenac Injection	25mg/ml	1 ml	1.49
41	2870(E)	9/20/2013	Cefixime Trihydrate+ Ofloxacin Tablets	Each Tablet Contains Cefixime Trihydrate eq.t Anhydrous Cefixime-100mg Ofloxacin-100mg	1 Tablet	5.5
42	2871(E)	9/20/2013	Cetrizine HCl+Ambroxol HCL Tablets	Each film Coated Tablet contails Cetrizine HCL-5mg Ambroxol-60mg	1 Tablet	3.15
43	2872(E)	9/20/2013	Omeprazole+Domperidone Capsule	Each capsule contains Omeprazole 20mg (as enteri coated granules) Domperidone-10mg	1 Capsule	4.32
44	3328(E)	11/5/2013	Magnesium Sulphate Injection	500 mg /ml	1 ml	4.96
45	3329(E)	11/5/2013	Phenytoin Sodium Injection	50 mg/ml		
46	3330(E)	11/5/2013	Clotrimazole Pessaries	100 mg	1 Pessaries	8.47
47	3331(E)	11/5/2013	Acyclovir Injection	500 mg/pack	Each Pack	433.81
48	3332(E)	11/5/2013	Clindamycin Tablets	300mg	1 Tablet	13.09
49	3333(E)	11/5/2013	Cyclosporine Concentrate for Injection	100 mg/ml	1 ml	118.64

50	3334(E)	11/5/2013	L- Asparaginase Injection	5000 KU./pack	Each Pack	1183.92
51	3335(E)	11/5/2013	Melphalan Tablet	2 mg	1 Tablet	108.53
52	3336(E)	11/5/2013	Melphalan Tablet	5 mg	1 Tablet	182.06
53	3337(E)	11/5/2013	Mercaptopurine Tablet	50 mg	1 Tablet	8.93
54	3338(E)	11/5/2013	Paclitaxel Injection	30 mg / 5 ml	Each Pack	301.24
55	3339(E)	11/5/2013	Procarbazine Capsules	50 mg	1 Capsule	31.64
56	3340(E)	11/5/2013	Vinblastine sulphate Injection	10 mg/pack	Each Pack	284.9
57	3341(E)	11/5/2013	Daunorubicin Injection	20 mg vial/pack	Each Pack	353.69
58	3342(E)	11/5/2013	Chlorambucil Tablets	2mg	1 Tablet	45.22
59	3343(E)	11/5/2013	Phytomenadione Injection	10 mg/ml	1 ml	43.82
60	3344(E)	11/5/2013	Dextran-40 Injection	10%	1 ml	0.75
61	3345(E)	11/5/2013	Factor VIII Concentrate Injection	Dried	Each Pack	6080.43
62	3346(E)	11/5/2013	Omeprazole Capsules	40 mg	1 Capsule	6.12
63	3347(E)	11/5/2013	Hyoscine Butyl Bromide Tablets	10 mg	1 Tablet	2.83
64	3348(E)	11/5/2013	Condoms	--	1 Condom	6.56
65	3349(E)	11/5/2013	Diphtheria Antitoxin Injection	10,000 IU/pack	Each Pack	1156
66	3350(E)	11/5/2013	Rabies immunoglobin Injection	150 IU	1ml	1255.84
67	3351(E)	11/5/2013	Hepatitis B Vaccine Injection	--	1ml	101.09
68	3352(E)	11/5/2013	Measles Vaccine Injection	--	Each Pack	252.97
69	3353(E)	11/5/2013	Chloramphenicol Drops	1%	1ml	4.26
70	3354(E)	11/5/2013	Thiopentone Sodium Injection	1 gm powder	1 gm	46.88
71	3355(E)	11/5/2013	Desferrioxamine mesylate Injection	500mg	Each Pack	148.64
72	3356(E)	11/5/2013	Praziquantel Tablets	600 mg	1 Tablet	23.87
73	3357(E)	11/5/2013	Isoniazid Syrup	100 mg/5ml	1 ml	0.22
74	3358(E)	11/5/2013	Clotrimazole Pessaries	200 mg	1 Pessaries	12.71
75	3359(E)	11/5/2013	Efavirenz Capsule	200 mg	1 Capsule	23.16
76	3360(E)	11/5/2013	Ritonavir Capsule	100 mg	1 Capsule	34.22
77	3361(E)	11/5/2013	Diloxanide Furoate Tablets	500 mg	1 Tablet	1.61

78	3362(E)	11/5/2013	Sodium Stibogluconate Injection	100 mg/ml	1 ml	3.26
79	3363(E)	11/5/2013	Busulphan Tablets	2 mg	1 Tablet	3.41
80	3364(E)	11/5/2013	Etoposide Capsules	100 mg	1 Capsule	52.3
81	3365(E)	11/5/2013	Folic Acid Tablets	1 mg	1 Tablet	0.25
82	3366(E)	11/5/2013	Hydroxyethyl Starch (Hetastarch) Injection	6%	1 ml	0.74
83	3367(E)	11/5/2013	Digoxin Injection	0.25 mg/ml	1 ml	2.85
84	3368(E)	11/5/2013	5-Amino Salicylic Acid (5-ASA) Tablets	400 mg	1 Tablet	3.9
85	3369(E)	11/5/2013	Bisacodyl Suppository	5 mg	1 Suppository	7.97
86	3370(E)	11/5/2013	Ethinylestradiol Tablets	0.05 mg	1 Tablet	3.53
87	3371(E)	11/5/2013	Antitetanus Human Immunoglobin Injection	250 IU/pack	Each Pack	832.16
88	3372(E)	11/5/2013	Antitetanus Human Immunoglobin Injection	500 IU/pack	Each Pack	1387.23
89	3373(E)	11/5/2013	Neostigmine Tablets	15 mg	1 Tablet	4.63
90	3374(E)	11/5/2013	Betaxolol Hydrochloride Drops	0.25%	1 ml	3.99
91	3375(E)	11/5/2013	Terbutaline Sulphate Injection	0.5 mg/ml	Each Pack	8.75
92	3376(E)	11/5/2013	Lignocaine Hcl Injection	1%	Each Pack	6.87
93	3377(E)	11/5/2013	Sulphacetamide Sodium Drops	10%	1 ml	2.31
94	3378(E)	11/5/2013	Sulphacetamide Sodium Drops	20%	1 ml	2.33
95	3379(E)	11/5/2013	Azithromycin Tablets	500mg	1 Tablet	20.51
96	3380(E)	11/5/2013	Glibenclamide +Metformin HCL (Extended release) tablet	Each uncoated bilayered tablets contains Glibenclamide-5 mg Metformin HCL - 500 mg (in extended release form)	10's Tablet	25.66
97	3381(E)	11/5/2013	Olmesartan Medoxomil + (Metoprolol succinate Tablets (Olmetor M 25mg)	Each film coated bilayered tablet contains Olmesartan Medoxomil Ph.Eur 20 mg Metoprolol succinate - 23.75 mg eq. to Metoprolol Tartrate - 25 mg (as extended release form)	1 Tablet	8.46
98	3382(E)	11/5/2013	Olmesartan Medoxomil + (Metoprolol succinate Tablets (Olmetor M 50mg)	Each film coated bilayered tablet contains Olmesartan Medoxomil Ph.Eur 20 mg Metoprolol succinate - 47.50 mg eq. to Metoprolol Tartrate - 50 mg (as extended release form)	1 Tablet	9.39

99	3383(E)	11/5/2013	Telmisartan + Metoprolol succinate Tablets (Telday M 50mg)	Each film coated bilayered tablet contains Telmisartan 40 mg Metoprolol succinate - 47.50 mg eq. to Metoprolol Tartrate-50 mg (as extended release form)	1 Tablet	8.87
100	3384(E)	11/5/2013	Amoxycillin +Clavulanic Acid Dry Syrup/ Suspension (Clamchek Forte D.S.)	Each 5ml of the reconstituted suspension contains: Amoxycillin Trihydrate eq. to Amoxycillin - 400 mg Potassium Clavulantate Diluted eq. to Clavulanic Acid - 57 mg	1 ml	2.85
101	3385(E)	11/5/2013	Cefixime Trihydrate+ Ornidazole Tablets (Cefolac OZ Tablet)	Each film coated tablet contains Cefixime Trihydrate eq. to Anhydrous Cefixime-200mg Ornidazole-500mg	1 Tablet	16
102	3386(E)	11/5/2013	Voglibose + Metformin HCL (SR) Tablets	Each uncoated bilayered tablet contains Voglibose - 0.2mg Metformin HCL - 500 (as sustained release)mg	1 Tablet	5.5
103	3387(E)	11/5/2013	Ceftriaxone Sodium + Sulbactum Sodium Injection	Each vial contains Sterile Ceftriaxone Sodium eq. to Ceftriaxone - 1 gm Sterile Sulbactum Sodium eq. to Sulbactum - 0.5 gm	1 Injection	110.99
104	3388(E)	11/5/2013	Voglibose + Metformin HCL (SR) Tablets	Each uncoated bilayered tablet contains Voglibose - 0.3mg Metformin HCL - 500 (as sustained release)mg	1 Tablet	5.8
105	3389(E)	11/5/2013	Paracetamol Drops (Macfast Drops)	Each ml contains Paracetamol - 100mg	1 ml	1.21
	3390(E)	11/5/2013	Cefixime Drops (Cefolac Drops)	Each ml of reconstituted suspension contains Cefixime as Trihydrate eq. to Anhydrous Cefixime - 25 mg	1 ml	3.49

Dated: 2nd October, 2013

National Pharmaceutical Pricing Authority

Sub: List of 55 medicines included in Schedule - I of DPCO, 2013 for which no information is available and prices could not be fixed/notified.

Sl. No.	Section	Name of drug	Dosage Form	Strength
1.	6.5.3.1	Pyrimethamine	Tablets	25mg
2.	18.8	Iodine	Solution	8mg / 5ml
3.	27	Vitamin D (Ergocalciferol)	Capsules	0.25mg
4.	27	Vitamin D (Ergocalciferol)	Capsules	1mg
5.	8.2	Actinomycin D	Injection	0.5mg
6.	6.5.4	Pentamidine Isothionate	Injection	200mg
7.	6.4.2.3	Ritonavir	Syrup	400mg / 5ml
8.	4.2	Sodium Thiosulphate	Injection	250mg / ml
9.	4.2	Sodium nitrite	Injection	30mg / ml
10.	17.6.2	Zinc Sulfate	Syrup	20mg / 5ml
11.	1.2	Lignocaine Hydrochloride	Spinal	5% + 7.5% Glucose
12.	1.1	Ether	Inhalation	--
13.	4.2	Flumazenil	Injection	0.1mg / ml
14.	4.2	Pralidoxime Chloride (2-PAM)	Injection	25mg / ml
15.	4.2	Methylthioninium Chlordie(Methylene blue)	Injection	10mg / ml
16.	4.1	Activated Charcoal	Oral	--
17.	19.1	Tuberculin, Purified Protein derivative	Injection	1TU
18.	19.1	Tuberculin, Purified Protein derivative	Injection	5TU
19.	6.4.2.3	Saquinavir	Capsules	200mg
20.	5	Sodium Valproate	Syrup	500mg
21.	1.3	Diazepam	Suppository	5mg
22.	1.3	Diazepam	Syrup	2mg / 5ml
23.	4.2	Penicillamine	Tablets	250mg
24.	6.1.1	Piperazine	Tablets	4.5gm
25.	6.4.2.3	Indinavir	Capsules	200mg
26.	8.1	Cyclosporine	Capsules	10mg
27.	26.3	Water for Injection	Injection	2ml

28.	26.2	Potassium Chloride	Injection	11.2% Sol.
29.	6.4.2	Stavudine	Capsules	15mg
30.	4.2	Atropine Sulphate	Injection	1mg / ml
31.	13.5	Dithranol	Ointment	0.1-2%
32.	4.2	Dimercaprol	Injection in oil	50mg / ml
33.	13.4	Zinc Oxide	Dusting Powder	–
34.	13.2	Neomycin + Bacitracin	Ointment	5 mg + 500 IU / g
35.	15.1	Gentian Violet	Paint	0.5%
36.	14.2	Sodium MeglumineDiatrizoate	Injection	76% w/v(Iodine conc. =370 mg / ml)
37.	14.2	Sodium MeglumineDiatrizoate	Injection	60% w/v(Iodine conc. =292 mg / ml)
38.	14.2	Propyliodone	Oily, suspension	500-600 mg / ml
39.	15.1	Chlorhexidine	Solution	5% (conc. for dilution)
40.	8.2	Cyclophosphamide	Tablets	200mg
41.	6.4.2.3	Nelfinavir	Capsules	250mg
42.	14.1	Lignocaine	Eye drops	4%
43.	14.2	Meglumine Iotroxate	Solution	5-8 g iodine in 100-250 ml
44.	14.2	Meglumine Iothalamate	Injection	60% w/v (iodine =280 mg / ml)
45.	27	Nicotinamide	Tablets	50mg
46.	6.2.4	Isoniazid	Tablets	50mg
47.	14.2	Barium Sulphate	Suspension	100% w/v
48.	14.2	Barium Sulphate	Suspension	250% w/v
49.	14.2	Calcium Ipodate	Injection	3g
50.	14.2	Iopanoic Acid	Tablets	500mg
51.	11.1	Fresh frozen plasma	Injection	
52.	11.2	Cryoprecipitate	Injection	
53.	11.2	Platelet Rich Plasma	Injection	
54.	11.1	Polygeline	Injection	3.5%
55.	11.2	Factor IX Complex (Coagulation Factors II,VII, IX, X)	Injection	Dried

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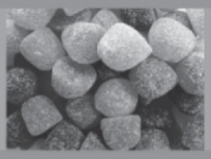

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Splenda Sucralose

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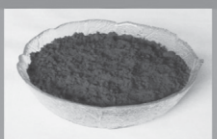

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INFORMATION

M. PHARM & PHARM D SCHOLARSHIP 2013 - 2014

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awards scholarships to selected **M. Pharm final year students and Pharm D** from various colleges in Tamilnadu for their on-going project work.

The scholarship scheme was initiated in the year 1998. The received applications are codified, so that the identity of the student is not disclosed to the evaluator and sent to institutions outside the state of Tamilnadu for evaluation.

This was the 16th year of these awards. This year we have included Pharm D also - Pharm D. Pharmacy Practice and Pharm D. Clinical Pharmacy. We received **134 applications** from eight different branches of Pharmacy. All synopses were sent to **Dr. G. Krishna Mohan,** Professor & Chairman - Board of Studies, Centre for Pharmaceutical Sciences, Institute of Science & Technology, Jawaharlal Nehru Technical University, Hyderabad and his team for evaluation. Based on their best marks, **24** students have been selected for award for scholarship as per the following details:

First Rank — Rs. 10,000/- each for 8 candidates.

Second Rank — Rs. 8,000/- each for 8 candidates

Third Rank — Rs. 6,000/- each for 8 candidates

COLLEGE-WISE BREAK-UP

Name of the college		Awards	Received
1. J. S. S. College of Pharmacy, Ooty	:	**10**	44
2. SRIPMS, Coimbatore	:	*	10
3. Periyar College of Pharmacy, Trichy	:	*	2
4. K. M. C. H. College of Pharmacy, Coimbatore	:	*	2
5. P. S. G. College of Pharmacy, Coimbatore	:	**2**	12
6. Vel's College of Pharmacy, Chennai	:	*	1
7. Adiparashakthi College of Pharmacy, Melmaruvathur	:	*	1
8. Sri Ramachandra College of Pharmacy, Chennai	:	4	14
9. Madras Medical College, Chennai	:	5	25
10. Madurai Medical College, Madurai	:	1	13
11. SRM College of Pharmacy, Chennai	:	2	9
12. C. L. Baid Mehta College of Pharmacy Chennai	:	*	1
TOTAL		**24**	**134**

SUBJECT-WISE BREAK-UP

Subject		Applications	First	Second	Third
Pharmaceutics	:	36	1	1	1
Pharmaceutical Chemistry	:	04	1	1	1
Pharmaceutical Analysis	:	21	1	1	1
Pharmacology	:	15	1	1	1
Pharmacognosy	:	10	1	1	1
Pharmacy Practice	:	15	1	1	1
Pharm D - Pharmacy Practice	:	18	1	1	1
Pharm D - Clinical Pharmacy	:	15	1	1	1
	TOTAL	134	8	8	8

RESULT

PHARMACEUTICS

Rank	Name	Institute	Amount
First	Mr. S. Karthik	PSG College of Pharmacy, Coimbatore	Rs. 10,000/-
Second	Mr. Uday Krishna Baruah	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Third	Ms. Vianni Chopra	JSS College of Pharmacy, Ooty	Rs. 6,000/

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institute	Amount
First	Mr. U. Jayaram	JSS College of Pharmacy, Ooty	Rs. 10,000/
Second	Mr. S. Vengatesh	Madras Medical College, Chennai	Rs. 8,000/-
Third	Mr. C. Sathiyaraj	Madras Medical College, Chennai	Rs. 6,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institute	Amount
First	Mr. M. Preetham Reddy	JSS College of Pharmacy, Ooty	Rs. 10,000/-
Second	Mr. Bandarupalli Chiranjeevi	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Third	Ms. Kota Saranya	SRM University, Chennai	Rs. 6,000/-

PHARMACOLOGY

Rank	Name	Institute	Amount
First	Mr. J. Sivaraman	Madras Medical College, Chennai	Rs. 10,000/-
Second	Mr. Gonala Vijay Kumar	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Third	Ms. Radhika Ramaswamy	Sri Ramachandra University, Chennai	Rs. 6,000/-

PHARMACOGNOSY

Rank	Name	Institute	Amount
First	Ms. S. R. Nandhini	Madurai Medical College, Madurai	Rs. 10,000/
Second	Ms. T. Muthu Lakshmi	Madras Medical College, Chennai	Rs. 8,000/-
Third	Ms. S. Zaburuth Nisha	Madras Medical College, Chennai	Rs. 6,000/-

PHARMACY PRACTICE

Rank	Name	Institute	Amount.
First	Ms. Megha Gupta	JSS College of Pharmacy, Ooty	Rs. 10,000/-
Second	Ms. Sheril Elsa Baby	Sri Ramachandra University, Chennai	Rs. 8,000/-
Third	Ms. Ritu Sebastian	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARM - D PHARMACY PRACTICE

Rank	Name	Institute	Amount.
First	Mr.K.Ganesamurthy & others	Sri Ramachandra University, Chennai	Rs. 10,000/-
Second	Mr. Prathap PPJ & others	Sri Ramachandra University, Chennai	Rs 8,000/-
Third	Mr. P. Raja Mani Teja	SRM University, Chennai	Rs 6,000/-

PHARM D- CLINICAL PHARMACY

Rank	Name	Institute	Amount
First	Ms. Esther Mary Soman & others	JSS College of Pharmacy, Ooty	Rs 10,000/-
Second	Mr. Gokul Gummadapu	JSS College of Pharmacy, Ooty	Rs 8,000/-
Third	Mr. G. Manas Kumar & others	PSG College of Pharmacy, Coimbatore	Rs 6,000/-

ESSAY COMPETITION 2013 - FOR FINAL YEAR B. PHARM STUDENTS

Tamilnadu Pharmaceutical Sciences Welfare Trust Conducted 3rd consqueative Essay Competition for the final year B.Pharm Students in Tamil Nadu and Puducherry, on the subject of the Competition Ethics in Pharmacy Practice and Pharmacists Role in Safety of Medicine for Welfare of Common Man".

RESULT

Rank	Name	Institute	Amount
First	Mr. M. Muthuraman	K. P. College of Pharmacy, Tiruvannamalai	Rs. 8,000/-
Second	Ms. S. Sharmila Banu	School of Pharmacy, Vels University, Chennai	Rs. 7,000/-
Consolation	Ms. M. Anitha	Mother Theresa Post Graduate & Research Institute of Health Sciences, Puduchery	Rs. 5,000/-
Consolation	Mr. D. Ashwin Kumar	Annai Veliankanni's Pharmacy College, Chennai	Rs. 5,000/-

COLLEGE-WISE BREAK-UP

S. No	Name of the college	Received	Awards
1.	**Kamalakshi Pandurangan College of Pharmacy, Tiruvannamalai**	**1**	**1**
2.	Nandha College of Pharmacy, Erode	1	
3.	S. Chattanatha Karayalar College of Pharmacy, Tirunelveli	1	
4.	SRIPMS, Coimbatore	1	
5.	PGP College of Pharmaceutical Science & RI, Namakkal	1	
6.	S.S.M College of Pharmacy, Erode	1	
7.	R.V.S. College of Pharmaceutical Sciences, Coimbatore	9	
8.	**Annai Velankanni's Pharmacy College, Chennai**	**1**	**1**
9.	Arulmigu Kalasalingam College of Pharmacy, Krishnan Koil	5	
10.	PSG College of Pharmacy, Coimbatore	3	
11.	Adhiparasakthi College of Pharmacy, Melmaruvathur	3	
12.	**Mother Theresa Post Graduate and RI, Puduchery**	**8**	**1**
13.	K. K. College of Pharmacy	3	
14.	Ultra College of Pharmacy, Madurai	1	
15.	**Vels University, Chennai**	**3**	**1**
	TOTAL	**42**	**4**

INDUSTRIAL ORIENTED TRAINING PROGRAM ON QUALITY CONTROL OF DRUGS AND PHARMACEUTICALS FOR FRESH B.PHARM / M.PHARM GRADUATES

Tamilnadu Pharmaceutical Sciences Welfare Trust constituted an Institute under the name of "Pharm Knowledge Training Institute - Finishing School". The objective of the training Institute is to conduct various training programs / refresher courses for the Pharmacy graduates in order to update them the latest technology and knowledge. Initially we are going to conduct a Training program on Quality Control of Drugs and Pharmaceuticals for fresh B.Pharm and M.Pharm graduates during the third week of January 2014 for a period of one month. The Training program covers seven modules. Each module contains different aspects of subject's pertaining to Pharma Industry and also Quality Control and Regulatory Systems. Some of the important lectures includes overview of Pharmaceutical Industry Pharmaceutical legislation, Pharmacopeias, different type of testing of Pharmaceuticals, Good Laboratory Practices, SOP's, Instrumental Analysis, Microbiological Testing's, Monitoring of Air system and Water system calibration and Validation of analytical equipment, stability studies and records maintenance. The lecture program are covered in the first 15 days and the remaining 15 days the candidates are positioned in various Pharma manufacturing unit in Chennai for the practical training on various types of analysis. After the completion of the one month training program the Pharma companies in Chennai will be conducting interview for the placement of the trainees. We have prescribed minimum fees of Rs. 10,000/- for this training program for each candidate, the trainees will be given snacks, tea and lunch during this training program.

We have forwarded the complete brochure of the training program to all the Principals of the Pharmacy colleges in Tamilnadu and Puduchery for sponsoring the candidates. We request all our readers and college principles and faculties to encourage the fresh graduates to enroll them as trainee in this program. The last date of receipt of the enrolment of the trainee is 10th of Jan 2014.

The candidates who are interested are required to send their biodata along with a proof of graduation and a demand draft for Rs. 10,000/- in favour of "Tamilnadu Pharmaceutical Sciences Welfare Trust" to the following address.

The Chairman Pharma Knowledge and Training Institute,
Tamilnadu Pharmaceutical Sciences Welfare Trust,
Block AB - Basement, Baid Metha Complex
16, Anna Salai, Little Mount, Saidapet
Chennai - 600 015.

Note: in case of any clarification they may contact the course coordinators namely
1. Mr. R. Narayanaswamy - 9790923549
2. Mr. K Prafulla Chandra - 9445515295

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EVENTS

52ND NATIONAL PHARMACY WEEK CELEBRATION

Report on 52nd National Pharmacy Week Celebration 2013 by IPA TN Branch

The National Pharmacy Week celebration was celebrated by Indian Pharmaceutical Association, Tamilnadu Branch, from 17th – 23rd Nov 2013 with various activities. In order to promote awareness to the public about importance of Pharmacists in community, pamphlets were distributed to all the retail shop outlets with the help of State Drugs Control Officials.

On the Second Day, a seminar on Community Pharmacy was organized at GRT Grant Hotel, T Nagar, Chennai, In association with IPA head quarters, Pfizer Ltd and Apollo Pharmacy. In the seminar Miss Emme Andrew, Director, External medicine affairs, Uganda, Mr. Raj Vaidya Practicing Community Pharmacist and Dr. G. Kannan, Professor of SRMC University, Chennai delivered lectures on the role of community pharmacists in Health care system.

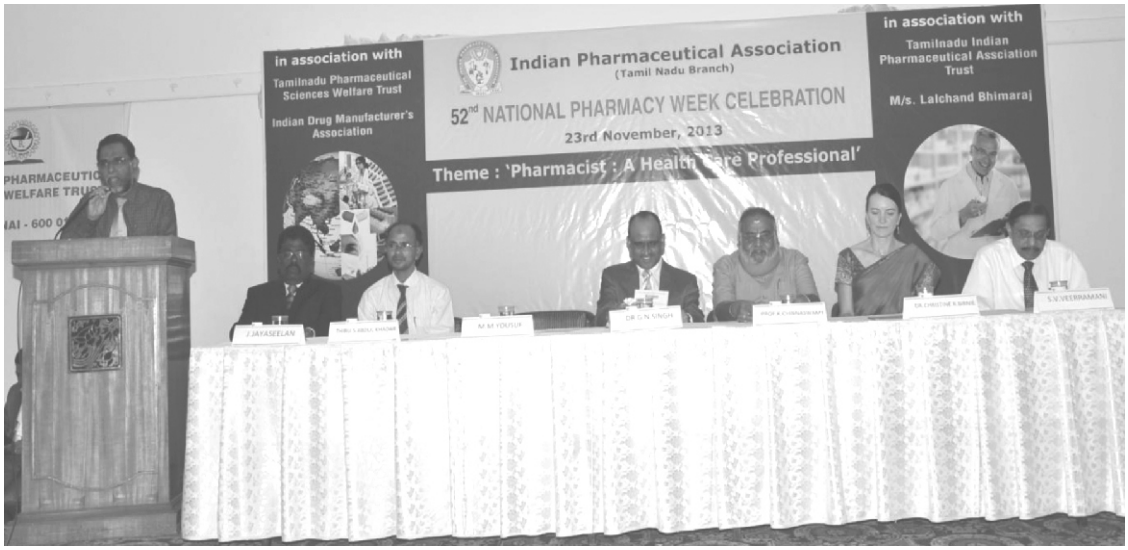
On the Third Day, our Association members Mr. R Sabapathy, of M/s. Medopharm and Mr. T. Sathish, of M/s. Tablet (India) Ltd., and Mr. A. Arunachalam, (Retd.) Joint Director of Drugs Control, Tamilnadu organized health awareness programme for Pharma industrial workers.

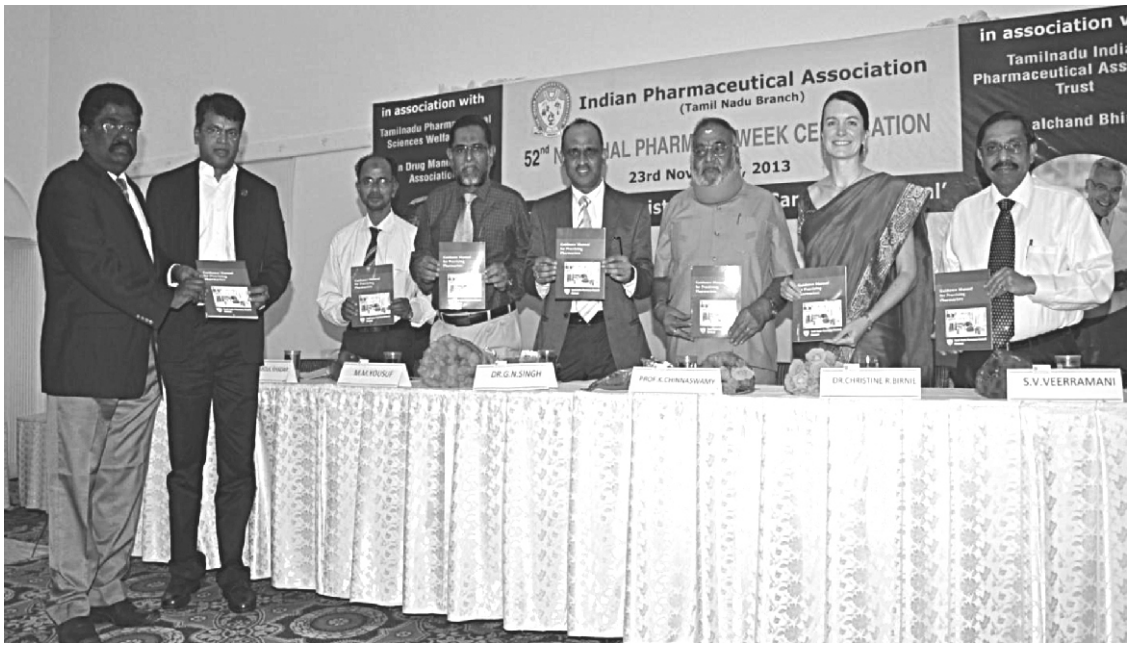
On the Fourth Day, a Blood Donation camp was organised in association with Jaya College of Pharmacy, Thirunindravur and Annai Veilankanni's Pharmacy College, Chennai.

On the Fifth Day, our association arranged a mega rally numbering 700 pharma students and professionals in Marina beach In order to promote and propagate the importance of pharmacists to the general public about the responsibility of Pharmacist in providing total health care system to the common people".

On 23rd Nov 2013 a validictory function was organised at Hotel Ambasodor Pallava, Chennai. Dr. G. N. Singh. Drugs Control General of India was the Chief Guest, Mr. S. Abdul Khader, the Director of Drugs Control, Tamilnadu was the Guest of Honour. Prof. K. Chinnaswamy presided over the meeting and Dr. Christine R Birnie, Associated Professor, Pharmaceutical Sciences, St. John Fisher College, USA delivered lecture on the theme of the Pharmacy week celebration. A guidance document on "Manual for Practicing Pharmacist" was also released by IPA (TN) which was prepared by Prof. K. Chinnaswamy, the President of Tamilnadu Pharmacy Council and Mr. T. Ilango, the Registrar of Tamilnadu Pharmacy Council the valedictory function day. Mr. A. M. Sulaiman, the leading industrialist who has industries all over India was awarded the "Best Pharmacists of the year

2013".Scholarship were distributed to M.Pharm and Pharm D students during this function. Awards were also distributed to the winners of Essay Competition for final year B.Pharm students which was instituted in the memory of "G. Swaminathan M.P." of M/s. Pharm Products, Thanjavur.





Periyar College of Pharmaceutical Sciences, Trichy

Periyar College of Pharmaceutical Sciences (PCPS) organized National Pharmacy Week Celebration from 18th to 23rd Nov 2013 in Trichy. The celebration started with various events like distribution of pamphlets about the theme "Pharmacist – A Health Care Professional" and followed by a rally in Trichy City to create awareness among public about the role of Pharmacist in the community. The rally was flagged off by Thiru J.J.L. Gnanaraj, President, Chamber of Commerce, Thiruchirappalli and Prof. P. Subramanian, Co-ordinator, As a part of NPW Celebrations, AICTE sponsored National Seminar on "Current Trends in Immunomodulators" was organized by the Dept.of Pharmacology and also a Pharma Quiz programme was organized for all Pharmacy students.Prof. N. S. Jegenathan, Director (R& D) PCP delivered lecture on the theme "Pharmacist – A Health Care Professional"

KK College of Pharmacy, Chennai

Pharmacy Week was celebrated by K.K. College of Pharmacy, Chennai by Organising a "Inter Colligiate Scientific Poster Presentation Competition" for Pharmacy students. Dr. T. K. Ravi of Principal of SRIPMS, Coimbatore delivered lecture on the theme "Pharmacist: A Healthcare Professional". A college magazine along with Pharmaceutical Analysis Book was released during this function by Prof. K. R. Arumugam. The Guest of Honour Shri M.M. Yousuf, Former Joint Director of Drugs Control, Govt. of Tamilnadu spoke about the various opportunities for the pharma graduates.Director (R& D) PCP delivered lecture on the theme "Pharmacist – A Health Care Professional"

PHARMACIST DAY CELEBRATION

The SRM College of Pharmacy, SRM University, celebrated 'Pharmacist Day' on 25th September 2013, in collobration with Indian Pharmaceutical Association - TN Branch. The International Pharmaceutical Federation (FIP) strongly recommends to commemorate 'World Pharmacist Day' on 25th September every year.

It can be proudly said that SRM College of Pharmacy was the first to celebrate the inaugural 'Pharmacist Day' in the whole of Tamil Nadu this year. The day's events began with a welcome address by Dr. K.S. Lakshmi, Dean, SRM College of Pharmacy, SRM University, and presided by Dr. M. Ponnavaiko, Vice-Chancellor, SRM University. The Chief Guest for the day was Thiru.S.Abdul Khader, Director of Drugs Control, Tamil Nadu, who enlightened the audience with several noteworthy proceedings of his department. The keynote speech by Thiru.T.Elango, Registrar, Tamil Nadu Pharmacy Council, served as a facelift for the pharmacists in the healthcare system.

DR. G. N. SINGH, DCGI VISIT TO CHENNAI

Dr. G. N. Singh, Drugs Controller General (India) visited Chennai on 22.11.2013. In the meeting organised by Deputy Drugs Controller (India) of CDSCO South Zone Chennai at Central Drug Testing Laboratory (CDTL) premises for interaction with members of IDMA TN Branch and PMA TN Branch on 22nd Nov 2013, Pharma Manufacturers requested DCGI to decentralize licensing in zonal level for quick disposal of various applications and also disposal of Fixed Dose combination. Dr. GN Singh also inaugurated the opening ceremony of Cosmetics Instrument room in CDTL, Chennai.

TARIFF FOR ADVERTISEMENTS

The members of the Tamilnadu Pharmaceutical Science Welfare Trust desire to accept and publish important advertisements in Pharma Web, from Pharma and allied industries, Pharmacy colleges, etc. The following are the tariff :

Back Cover	**Rs. 6,000/-**
2nd and 3rd Cover	**Rs. 4,000/-**
Full Page	**Rs. 3,000/-**
Half Page	**Rs. 2,000/-**

Advertisement size

Page size : 24 cm x 18.5 cm

Print area : 20 cm x 16 cm

Advertisers may send the cheque in favour of **'Tamilnadu Pharmaceuticals Sciences Welfare Trust"** to the address of the Trust along with the advertisemen matter is soft copy.

Note: 20% discount on the above rates for four consecutive issues.

The above revised tariff are effective from next issue.

NEWS

Medical Device Cos Say Don't Punish All For Quality Lapse

The medical devices industry has urged the government not to hold all players in the supply chain responsible in case a quality lapse is detected in a device. Indian and foreign firms operating in the country have separately written to different arms of the government, seeking a change in the Drugs and Cosmetics Bill that they say could lead to booking of even raw material providers and component suppliers in the supply chain in case of a faulty device.

While foreign firms have submitted that brand owners marketing the device should be held responsible for violations, domestic manufacturers have said accountability should be that of the marketing firm as well as primary manufacturer responsible for the final assembly of the product at its plant.

Medical devices made in India remain largely unregulated, barring a few exceptions that have been put under regulation since 2005 but are treated under the definition of drugs. The government plans to bring a new law to correct this by creating an exclusive set of rules for medical devices, a sector that is estimated at about Rs 18,700 crore and is growing at a CAGR of about 15%.

While defining the scope of regulation for medical devices, the Drugs and Cosmetics Bill 2013, introduced in the last session of Parliament, describes 'manufacture' of devices as "any process or part of process for making, assembling, altering, ornamenting, finishing, packing, labelling, or adapting any medical device with a view to its sale or stock or export or distribution but does not include assembling or adapting a device already on the market for an individual patient".

AdvaMed, a grouping of top medical devices multinationals, has requested the government to use the word manufacturer instead of 'manufacture'. "The ultimate legal responsibility for ensuring compliance should lie with the 'manufacturer', which, according to global guidelines, is the legal or natural manufacturer marketing the device. This would exclude cases where the devices are mishandled during transportation, storage or usage," said Gautam Khanna, chair, India Working Group, AdvaMed and country business leader,3M, a US-headquartered conglomerate.

The domestic firms insist that the definition should also include the primary manufacturer in whose plant premises the device has been assembled finally. "The 'manufacture' of medical devices has been defined on the same lines as for drugs whereas manufacture of a medical device is quite different from drugs," said Rajiv Nath, joint-managing director, Hindustan Syringes and Medical Devices and forum coordinator of AIMED, an industry body of domestic medical devices firm.

Source: *The Economic Times, 5th December 2013*

Firm That Learns From Others' Mistakes is More Successful: Dilip Shanghvi, Sun Pharma

What do you think about Indian pharma industry's recent run-in with regulators?

My sense is that Indian companies historically used to sell in unregulated markets. But increasingly now, a large part of the business is coming out of regulated markets. So, the understanding and assessment of requirements - structurally and organisationally - are important transition points. Also, FDA's expectations on quality and what should be manufacturers' responsibility are an evolving process. They say that in pharma, the current good manufacturing practice and 'C' are very important. So, what is GMP today might not be GMP tomorrow - it is a constantly evolving expectation. So, I think the structure is important so that people within the organisation, those who manage these processes, have the requisite power and authority to ensure that changes are managed effectively. Indian companies aren't an exception here, because many international companies, including large pharma companies and innovation-based companies, are also going through this process. So, you cannot single out India and you can't single out small and generic companies. It is across-the-board.

Do you think Indian pharma success stories built over 15 years have taken a beating?

Personally, I feel that a company, which looks at problems of other companies and learns from their mistakes, is a successful one. I would look at this as a learning opportunity rather than a credibility issue.

Has the FDA increased scrutiny?

My understanding is that after the low molecular weight happened in the US, Congress wanted the FDA to have a very consistent foreign manufacturing location inspection policy -all this is the result of that. FDA set up its first international office in China, the next one in India. So, it's like we have a manufacturing facility in the US and FDA visits us frequently. I think FDA's concerns are patient-safety.

What has been your learning post the Caraco FDA issue. How did you meet the required compliance?

I think, the Caraco issue taught us that we need to treat manufacturing as a global function. Since we were structured differently earlier, we had Caraco as a self-sustained single unit that had its own infrastructure for everything. Now, we are changing our structure. Technology and operations will report globally. We have a central global manufacturing compliance and global quality. We are putting in place practices and processes that are more in line with major regulatory bodies. We are working with them.

Sun gets a lot of revenue from the US. But the US market is also challenging. Regulatory issues apart, the market is highly competitive. What do you think Sun needs to do?

The US is a large part of our business. But for the US, we are a very small company. We are not a very large company by US standards, so to that extent, we have the opportunity to grow our business. But the pharma market in general, irrespective of the US, is changing dramatically. That's because of the financial constraints faced by various governments and the current international pressure on healthcare. The other major challenge for the industry is managing innovation and what you call better understanding of patients and their needs: the ability to, let's say, tailor the treatment for specific individuals. Because as science evolves, our understanding will change and that change should allow regulatory agencies to approve drugs in the process to what it was 20 years ago.

We try and stay focused on execution, understanding customer needs, innovation and cost. So, all these key drivers make the business more successful.

This quarter we saw three drugs have pepped up your numbers. How does Sun Pharma look post-2015?

This is something I have shared in the past. My limitation is that I don't have a clear vision beyond this year. I try to stay focused on what I need to deliver this year. As for the next year, we try and see that we remain consistent. So, our focus is to see that we are growing faster than the industry. And whichever product we launch, we do better than competition. We try and manage our operations better than competition. Essentially, we try to be better than what we were the previous year.

Do you think Sun Pharma still has a lot of ground to cover?

I think, we have a long way to go before we can be happy.

Many companies want to be like Teva. How do you plan to achieve that?

You cannot be as big as Teva doing what Teva did 10 years ago. You have to do things very differently. Because environment has changed, market dynamics have changed and you have to adopt your strategy to the current environment.

How will you focus on your product portfolio?

We want our business to develop balance-of portfolio products that will allow us to grow rather than have a one growth engine; we want to have multiple engines of growth. So dermatology would be one of the important growth strategies, others would be specialty business within generic business. As of now, we have small business coming from Europe, but no business in Japan. So, we have to find a way to overcome these challenges.

Sun Pharma has a lot of cash on its books and you have done successful acquisitions. Do you plan more acquisitions?

We will look at opportunities to buy new businesses provided they fit in with valuation norms. So far, we have been disciplined about what we buy.

What are the key things you will look for?

Basically, you will look at any acquisition on a financial model. You do not put costs related to culture and management time spent for integration. And you have to be (aware) that all these things will happen. There would be huge cultural issues; there would issues where the senior management time will be spent in integration. If that happens, the base business suffers. We try to keep these in mind while buying. Fortunately for us, most of our acquisitions have worked. Not only in terms of EPS, but also value creation, given the depth of products in technology. That's our approach: post-acquisition, we don't just become a bigger company, but a company with better understanding of technology. With Dusa, we have got access to dermatechnology, which helps us to look at new range of products. So, in a way we have been disciplined, we don't look at EPS accretion as the only reason of transaction. Specific products, market access and customer relationship are what we look for.

Some Indian companies seem to be moving away from India and investing abroad. Do you think India has lost the investment edge?

I think we are a meaningful player in India in terms of size and market share. So whenever we look at any business, we look at the opportunity to develop synergy to justify the acquisition. Synergy can be in terms of cost, market access and product range. If we make an acquisition that will help us get a justifiable synergy, we will do it. We continue to do green-field investments. On an average, we invest $150 million in green-

field or brown-field ventures. Pharma industry is not like power, we don't need so much space, water and we don't make much of an environmental impact. We have problems like the FDA.

FDI in Pharma has become controversial. The government wants to restrict it and it took the PMO's pressure to get the Mylan-Strides deal approved. DO you think the Indian government is doing the right thing?

My personal sense is that, Pharma industry within the country is so diverse as well as fragmented. If a company gets acquired its ability to price its products higher becomes limited. So the concern that multinational companies coming and buying the companies in India will push up the price of products for consumers is not big for or for the government. And the industry's view is that competition determines price, so competition itself should become a price control regulatory mechanism. But the Indian Pharmaceutical Alliance has supported the government in restricting FDI I don't think this is a correct assessment because I think IPA's view bout foreign companies investing in India is not in any way close to what is being reflected.

What do you think the Indian pharma sector should do - should it continue as a generics player, or should it go for innovation?

I think Indian firms should focus on becoming a much bigger generic player globally. They should also find a way to participate in the innovation business. It's a business which requires long-term investment. And it's a high-risk business, with high probability of failure. But if it is successful, and when it's successful, it generates value which is far beyond what a generic product will give. We believe that this is a great opportunity to find a way to succeed. We don't have a large history here; my sense is that a large number of skillsets necessary for success still needs to be evolved. I think it is matter of time.

Source: *The Economic Times, 4th December 2013*

Contraceptive Pills For Men to Be A Reality Soon

Scientists have taken a giant leap towards creating the world's first contraceptive pill for men. Researchers from University of Melbourne and the University of Leicester, UK, collaborated on the study. Publishing their results on Tuesday, scientists have found that complete male infertility could be achieved by blocking two proteins found on the smooth muscle cells that trigger the transport of sperm.

Currently, men can only use condom or undergo a surgical vasectomy as the proven form of contraception.

The researchers demonstrated that the absence of two proteins in mouse models, 1A-adrenoceptor and P2X1-purinoceptor, which mediate sperm transport, caused in fertility, without effects on sexual behavior or function.

Lead researchers Sab Ventura and Carl White of the Monash Institute of Pharmaceutical Sciences believe the knowledge could be applied to the potential development of a contraceptive pill for men.

Source: *The Times of India, 4th December 2013*

Designer Sperm' to Fix Faulty Genes?

Designer sperm' can be used to change faulty genes of future generations by introducing new, functioning genes, scientist have found. A study shows that introducing new genetic material via a viral vector into the sperm of mice leads to the presence and activity of those genes in the resulting embryos. This new genetic material is actually inherited, present and functioning through three generations of the mice tested.

This discovery could lead to a new frontier in genetic medicine in which diseases are cured, and new human attributes, such as organ regeneration, may be possible, scientists said.

Source: *The Times of India, 4th December 2013*

80% of Medicines Not Covered by Price Control Order

About 38 million people in India (which is more than Canada's population) fall below the poverty line every year due to healthcare expenses, of which 70% is on purchase of drugs. Yet, the much-awaited Drug Price Control Order (DPCO) 2013, meant to control the price of medicines does not cover over 80% of the medicines in the market. Many drugs crucial for India's disease profile have been left out, which means people are unlikely to see any significant reduction in expenditure on medicines.

In 2003, the Supreme Court, while hearing a case on the National Pharmaceutical Pricing Policy, had directed the government to formulate appropriate criteria to identify essential and life saving drugs and ensure that they came under price control. It took over a decade for the government to announce the DPCO in May 2013.

By the government's own admission in an affidavit filed in court, the market value and share of medicines covered by DPCO is just 18% of the country's pharma market. Many life-saving medicines including anti-cancer drugs, expensive antibiotics and drugs needed for organ transplantation have been left out.

The government merely lifted the entire National List of Essential Medicines (NLEM) 2011, comprising 348 medicines, and placed it under price control. "The literal translation of the NLEM into DPCO 2103 has been done without a thought of its implications. The companies have been provided a convenient escape route. A 500 mg Paracetamol tablet is under price control but its 650 mg strength is not; individual anti-TB drugs are under price control but their combinations which outsell single ingredient preparations are not. This undermines the entire objective of making essential medicines more affordable to Indians," explained Dr Anurag Bhargava, associate professor at the Himalayan Institute of Medical Sciences. He stressed the need to expand the scope of price control to include all dosages and combinations, as was the case in the previous DPCO of 1995.

With the current DPCO not covering combinations of drugs, a lot of drugs for diabetes and hypertension and many other conditions will move out of price control as they are used in combination. The combinations not covered under NLEM account for Rs 31,866 crore or almost 45% of the total pharma market of Rs 71,246 crore in 2012.

An independent evaluation of the National Pharmaceutical Pricing Policy, by the Public Health Foundation of India (PHFI) and the Institute for Studies in Industrial Development (ISID) for a forthcoming report explains why it is important to expand the scope of price control. According to their evaluation, the market value of anti-infectives under price control is Rs 4,636 crore, just 6.5% of the total market. Anti-infectives, which include antibiotics, have the biggest chunk of India's pharma market.

"Our evaluation shows that if price control was expanded to combinations, additional strengths and dosages of just the anti-infectives included in the NLEM, the total market value would be worth more than Rs 10,500 crore, about 15% of the total pharma market, a vast improvement over the current coverage of just 6.5%," said Malini Aisola of PHFI.

The essential medicines list does not seem to have taken into account India's disease profile as it leaves out several drugs crucial for treating many common conditions, pointed out Dr Bhargava. The government's own affidavit admits that only 18% of anti-diabetics, 19% of anti-TB medicines and 6% of the respiratory therapeutics segment are under price control. This is despite India being the diabetes and TB capital of the world, and facing high prevalence of asthma and chronic obstructive pulmonary disease (COPD).

There's good reason why we need price controls. The MRP charged by companies is often many times the cost of production leaving them with profit margins unheard of in any other sector. Price control was meant to address this problem, particularly in medicines important for India. But it has failed to make any significant difference.

One reason is the way prices are determined under the current DPCO. Under the 1995 DPCO, the drugs prices under controls was decided by taking the cost of manufacture and fixing a certain percentage as mark-up, which included packaging and distribution costs, retailers' margin, excise duty and profit. But the current DPCO uses a new formula under which the price is fixed by taking the average price of brands having one per cent or more of market share and adding 16% as retail margin.

S Srinivasan of LOCOST, a company producing drugs for use by NGOs to treat the poor, explained how the cost of manufacture, including retail margin, for Cetrizine, an anti-allergic, is just Rs 1.20 for ten tablets. The ceiling price under the DPCO is Rs 18.10, the same as the price charged by the market leader GSK. This allows a price that is 15 times the cost of manufacture. In the case of Albendazole, a drug used to treat worm infections, the cost of manufacture including retail margin is Rs 8.50 per 10 tablets, while the DPCO ceiling price is over Rs 91, a ten-fold mark-up, pointed out Srinivasan. The price charged by the market leader in Albendazole, GSK, was Rs 140 per ten tablets. In this case, while price control should bring down the market leader's price, it still allows a huge profit margin. In fact, the PHFI-ISID evaluation shows that in 43% of drugs studied, the sales leader will face little or no impact from price control.

To show how effective DPCO has been, the government has compared the price reductions due to DPCO with the highest price of a drug. However, PHFI and ISID point out, it makes more sense to use the price charged by the company with the highest market share for comparison. Out of the 390 formulations for which prices have been notified, in 212 the company with the highest sales does not have the highest price. So, the price reduction achieved by DPCO is nowhere as dramatic as claimed by the government. PHFI and ISID have conducted an independent analysis using the same data as used by the government. Their calculation for 369 formulations shows that the effective average price reduction would be just 11% and the impact on the pharma market as a whole would be a mere 1.8%.

In sum, coming in 2013, a decade after the Supreme Court asked for it, the DPCO is clearly late. But even worse, as the PHFI-ISID study reveals, it is too little. Given how much rides on this for the aam aadmi, that is a tragedy of mammoth proportions.

Source: *The Times of India, 2nd December 2013*

Cabinet Rejects FDI Cap in Pharma

The Union Cabinet rejected a proposal to limit foreign direct investment in domestic manufacturers of "rare and critical" drugs, a move that should boost sentiment and come as a relief to overseas companies looking to acquire Indian pharmaceutical companies.

The department of Industrial Policy and promotion (DIPP) had proposed a 49% limit in so-called brownfield projects, as opposed to the absence of any cap now, on fears that unfettered acquisitions could drive up the cost of medicines in India.

"We are not going to reduce the FDI cap in brownfield pharmaceuticals for the moment," commerce and industry minister Anand Sharma told reporters on Friday.

India had allowed 100% FDI in the pharmaceutical sector through the automatic approval route in 2002. The finance ministry was opposed to the DIPP proposal, arguing that such a stance would hurt the country's image as an investment destination.

In the Cabinet discussion on Thursday, finance minister P Chidambaram said such a policy was not in sync with the country's overall plan to open up, according to a person aware of the discussion. While some cabinet ministers backed Chidambaram's view, the department of pharmaceuticals and the Planning Commission expressed reservations on changing the policy at this juncture, the same person added.

In its note to the Cabinet, the finance ministry had pointed out that the policy had been reviewed only about a year ago and that it was too short a period to assess its impact.

In a review of the country's pharmaceutical policy a year ago, Prime Minister Manmohan Singh had approved the imposition of conditions that included mandatory investment in research and development and manufacturing of drugs produced by the acquired pharma company.

DIPP had also sought to prevent foreign investors from divesting stakes in manufacturing and R&D facilities in cases of transfer of ownership, besides imposing a three-year lock-in on investment. The proposal also included a non-compete clause for the Indian seller and a mandatory 25% investment in research by the stake-acquiring company.

In the new policy, "rare and critical" covers drug segments that have just five Indian manufacturing units, besides entities having a 40% share of the domestic market. A facility will also be considered as coming under this classification if either of these two conditions is fulfilled for at least a third of its products. Last year, the government introduced a distinction between greenfield and brownfield projects over concerns that Indians will be denied cheap medicines if multinational companies continue to buy Indian firms. The government put FDI in existing Indian pharma companies on the approval route, but continued to allow 100% in greenfield units as part of the new policy approved by Singh.

The recent bid to tighten policy was triggered by US-based Mylan's acquisition of Agilia Specialities, a company that makes mostly oncology drugs.

Acquisitions by overseas companies over the last few years include that of Matrix Laboratories by Mylan, Ranbaxy Laboratories by Daiichi Sankyo and Piramal's Healthcare Solutions division by Abbott.

Other companies that have seen a rise in foreign holding in recent years are Dabur Pharma, Shanta Biotech and Orchid Chemicals.

On November 28, ET reported that global buyout fund KKR is to acquire a 35% stake in Hyderabad-based Gland Pharma, which makes niche cardiovascular and orthopaedic drugs.

Source: *The Economic Times, 30th November 2013*

IPAB Revokes Kibow Biotec's Patents

The Intellectual Property Appellate Board (IPAB) has ordered the revocation of patents granted to U.S.-based Kibow Biotech Inc for its pharmaceutical compositions meant for treating renal, hepatic and gastrointestinal diseases at the same time.

The board passed the orders on applications filed by La Renon Health Care Pvt. Ltd, a competitor in the pharmaceutical market, who sought to revoke the patents of Kibow Biotech, on the ground that those patents lacked inventiveness.

Kibow Biotech is a biotechnology company which specialises in the development and clinically tested probiotic dietary supplements. The patent has been obtained by the company for the invention titled, 'Prebiotic and Probiotic Compositions and Methods for their Use in Gut-Based Therapies'.

The company claimed that its pharmaceutical compositions were providing for an integrated, gut-based low cost alternative treatment for renal insufficiency, liver insufficiency, inborn errors of urea metabolism and gastrointestinal disorders and diseases.

The impugned invention would alleviate at the same time more than one symptom.

Seeking to revoke the patents granted to Kibow Biotech, the Gurajat-based La Renon Health Care filed the applications contending that there was no proof or description to support the statement that the invention would alleviate at the same time more than one symptom.

Therefore, Kibow's statement was very general and not supported by any appropriate description in the specification.

Concluding that Kibow's specification was not clearly substantiated, the Board, comprising its vice-chairman S. Usha and technical member D.P.S. Parmar said the compositions were mere admixture.

Source: *The Hindu, 23rd November 2013*

Cadila Launches Novel, Cheaper Cancer Drug

Ahmedabad-based Cadila Pharmaceuticals introduced the first novel product for cancer management which it claims is a significant breakthrough in the treatment of lung cancer.

Mycidac-C is an innovative research product for patients suffering from a cancer sub-type - non-small cell lung cancer - and will be priced at Rs 4,000 for 10 injections.

The total cost of therapy to patients is estimated at Rs 40,000 - which the company claims is affordable as cancer treatment is generally exorbitant. Cadila CMD Dr Rajiv Modi said on Thursday, "Our drug is a significant breakthrough in the management of squamous non-small cell lung cancer (NSCLC), since the introduction of first line cancer drugs nearly 30 years ago." As per World Health Organisation, approximately 1.25 million people are diagnosed with lung cancer every year worldwide. Lung cancer kills more people than the three next commonest cancers combined.

The drug has already been approved by the country's Drug Controller General. According to Dr Modi, the drug is the world's first targeted active immunotherapy, and is to be used in conjunction with other cancer medication. Final trials on the drug suggest that it improves median survival by over 40% in patients suffering from squamous NSCLC. "It has taken us over a decade, a huge investment and a dedicated research and development team to develop this unique drug. We expect it to be available in the Indian market by December 2013. Thereafter, we will introduce it in other regions like SAARC countries and European markets over the next five years".

Source: *The Times of India, 22nd November 2013*

Tough Times Await Indian Contract Drugmakers

Pharmaceutical companies that carry out contract manufacturing and research are in for tough times because of a fluctuating rupee, rising raw material costs and the looming expiry of tax incentives. Most of these companies have manufacturing facilities in Uttarakhand, Himachal Pradesh and the Jammu and Kashmir and were given a tax holiday of 10 years as incentive. Many of them are approaching the tenth year of operations. Added to this, the cost of raw materials, mostly imported from China, has soared.

For instance, the price of raw material for antibiotic amoxicillin has gone up from 1,450 a kg last year to 2,200, an almost 50% rise. Similarly, the imported hormone progesterone now costs 31,000 a kg while it was 15,000 just a few months ago.

These pharmaceutical firms are also receiving requests from clients to cut prices after the government imposed price ceilings on many essential medicines, forcing price-drops of as much as 60%. "We are finding it difficult to bluntly refuse the requests of big pharma clients, who are our bread and butter, to slash prices," said Bodh Raj Sikri of the Indian Drug Manufacturers' Association. He said profit margins for most players have come down by more than 300 basis points in one year.

There are about 700 firms in north India, operating in the contract research and manufacturing space, referred to as CRAMS. The market size of the segment is expected to be about $7.3 billion (45,300 crore) for 2013, according to Revati Kasture, head of CARE Research, who estimates the industry to grow 11-13% annually over the next two-three years.

Big pharma companies that buy from these firms include Dr Reddy's, Ranbaxy, Cadila, Sun Pharma, Mankind and Cipla. Utkarsh Palnitkar, KPMG India's head for pharma and life sciences, said the key challenges for contract manufacturers are raw material and transportation costs. "Competition from China is also a major threat the contract manufacturing organizations are facing. It has been reported that Indian companies have lost their contracts for paracetamol supply to Chinese companies in the beginning of the year." But it's the wayward rupee that is causing the maximum damage by making imported raw materials costlier. For instance, Akums Drugs and Pharmaceuticals gave the order for importing potassium clavulanic acid on June 1 when the dollar rate was about 55. By the time the order was executed, the dollar had touched 67. As a contract manufacturer, Akums Drugs charges its customers the rate at the time of placing the order. As a result, the company had to shell out an extra 76 lakh on this one ingredient alone.

"We have lost heavily on foreign exchange payments," said Sanjeev Jain, promoter-director of Akums Drugs. Almost 65% of the raw materials intermediates are imported by the manufacturers. Besides raw materials, costs of diesel, manpower and locally-made ingredients are also on the rise.

A senior official at a large pharma company, who did not want to be identified, admitted that his firm was asking for a price cut because of the government directive on prices.

Source: *The Economic Times, 20th November 2013*

Web Group Wants Clinical Trials to Continue In India

People for the Advancement of Clinical Research, (PACR) India, a group that claims to comprise ordinary healthy citizens, patients, government officials, health enterprise professionals, educators and patient advocacy groups have initiated a petition in the popular advocacy site change.org asking the Supreme Court to allow the review and approval process for clinical trial applications to resume.

The group in its petition has lashed out against NGOs that have been opposing clinical trials in the country on ethical grounds, and the media for its (mis)reporting on the issue. The groups fail to recognise that their often emotive and misinformed statements are only turning out to be more detrimental to the cause they espouse - protection of the research participant, the petitioners noted.

Clinical trial in India has become a controversial issue in the last two years, with a few health activists and politicians claiming that pharma companies and clinical research companies enrolled patients without their consent into trials and used them as guinea pigs in the name of research. Swasthiya Adhikar Munch (SAM) is one of the NGOs that had filed a public interest litigation against the health ministry and the drug controller for giving approvals to clinical trials without following proper guidelines. Following the PIL, the Supreme Court ordered the government to regulate trials. In September this year, the court stayed the approval of 162 trials and asked the drug controller to provide evidence that proper norms were followed for drug related research. PACR, which claims to be committed to setting the record straight about the importance of clinical research in India, has disputed most of the charges which NGOs like SAM have presented in court. They have also disputed the figures of people who died due to trials.

The data that 2,868 people died during clinical trials of 475 new drugs between 2005 and 2012

is very misleading and done purposely so that newspapers sell and websites attract visitors, the petitioners write. They say out of the estimated 451,000 people who participated in clinical trials between 2005 and 2012, 89 died of trial-related causes.

The Indian Society For Clinical Research (ISCR) in India, the official lobby group of clinical trial companies and pharma companies in India, has said the petition is encouraging as it comes from the stakeholders.

Source: *The Economic Times, 11th November 2013*

Drug Regulator Casts Shadow Over Suns Mumbai Laboratory

The Drug Controller General of India has ordered Sun Pharmaceutical, the country's largest drug maker by market capitalisation, to suspend clinical research activities at its Mumbai based bio-analytical Laboratory, a move that could slow down the companys regulatory filings in India and possibly overseas as well. According to officials familiar with the matter, the drug regulator took the step after discovering that Sun didn't have the requisite approval from the central government for operating the laboratory. The drug regulator has decided not to accept future applications and wont process existing new drug filings that Sun has made from the Mumbai lab until the company gets an approval. Sun has a similar laboratory in Vadodara.

Leading Indian drug makers have been facing increased scrutiny from global regulators with Ranbaxy Laboratories,Wockhardt and Strides Arcolab getting rapped by the US authorities earlier this year, but this is a rare instance of the domestic regulator taking stiff action against a company. A final decision to suspend clinical research at the affected centre was taken at a meeting on Monday last week when senior Sun Pharma executives met top Drug Controller General of India (DCGI) officials to explain the companys position. This meeting was preceded by an exchange of correspondence between the company and central drug regulators office. A Sun Pharma spokeswoman confirmed receiving a letter from DCGI and said the company was working with the authorities to resolve the issue quickly. She added that the company believed it has complied with all existing regulatory requirements.

Source: *The Economic Times, 8th November 2013*

City Racket Smuggling 'Viagra' Busted

Drug Inspectors Seized Distributor Sending Drug to Middle East Through Courier

Central drug control authorities raided a Mylapore-based pharma agency and seized sildenafil citrate (sold in the market also as Viagra) meant for smuggling abroad. The drug distributor had been sending the drug through courier to the Middle East and western countries. Investigations revealed that agencies in other states were also illegally smuggling out the drug through post and courier firms.

Based on a tip-off, officials of the Central Drugs Standard Control Organization (CDSCO) and the Tamil Nadu drug control authority raided the agency on Royapettah High Road and found huge quantities of the drug meant for export. Inquiries revealed that the agency sent the drug consignments through post offices where they were declared as genuine drugs. "As the agency violated the rules mentioned in the Drugs and Cosmetics Act, 1945, we are thinking of booking a separate case against it. This is only the tip of the iceberg. There are a lot of big sharks involved

in the racket across India," a CDSCO official said.

The officials have asked the agency to furnish the personal details of every user of the drug abroad. "Apparently, the agent who placed the orders with the agency for the supply of sildenafil citrate sent false medicinal prescriptions," the official said.

Preliminary inquiries revealed that many pharma agencies across the country were using similar modus operandi to send consignments of sildenafil citrate abroad without the manufacturer's consent. These agencies were buying bulk quantities of the drug directly from wholesale stockists and smuggling it out of the country, he said. "The dealers constantly get orders from many western countries, including the UK, where there is a great demand for the drug."

Soon after the raid, two directors of the pharma agency submitted a request to the drug control officials, seeking to surrender their drug licence. "We, however, have not closed their licence, as there are discrepancies in their claim. Moreover, we have frozen a pile of medicine stocks in the agency. The directors locked the agency and gave the key along with the indent to the security guard of the building," the official added.

Source: *The Times of India, 5th November 2013*

Pharma Sector Growth Slows to 9.8 Per Cent

The pharmaceutical market may have grown 10 per cent in value terms in 2013, but the sector as a whole witnessed lower growth of 9.8 per cent as compared to 16.6 per cent in 2012 due to several challenges faced by the industry, according to a report by the Confederation of Indian Industry (CII) and PwC.

The slowdown is due to the new drug pricing policy and the regulatory interventions over last year, says the report, released here on Thursday.

The Indian pharmaceutical market (IPM) has been now valued at Rs.72,069 crore as against Rs.65,654 crore in 2012, the report says..

"The industry is witnessing additional challenges like delays in clinical trial approvals, uncertainties over the FDI policy, a uniform code for sales and marketing practices and compulsory licensing. The slowdown is also evident from the number of new product launches, which has gone down from 1900 in 2010 to 1700 in 2012," the report adds.

Chronic therapies

According to the report, the contribution of chronic therapies to the IPM has gone up to 30 per cent in 2013 from 27 per cent in 2010. Chronic therapies (cardio, gastro, CNS and anti-diabetic) have outperformed the market for the past four years, and are growing at a rate of 14 per cent, faster than the acute therapies, which grew at 9.6 per cent.

As per the report, India is perceived as an attractive destination for clinical trials.

The industry is also facing stricter regulations on manufacturing and quality practices in the domestic as well as the international markets. Domestic companies will have to raise their compliance to U.S. FDA regulations as they drive their major share of exports from the U.S. market, the report adds.

"The implementation of the National Pharmaceutical Pricing Policy, 2012, by the government has resulted in margins erosion from 20 per cent and 10 per cent to 16 per cent and 8 per cent for retailers and stockists, respectively.

Source: *The Hindu, 2nd November 2013*

US Norms on Statins to Help Indian Drug Cos

Drugs worth nearly Rs 92,000 crore were sold in the US in the year to September 2013

Indian pharmaceutical companies may have struck a vein of revenue worth billions of dollars because of new recommendations in the US which could result in increased prescriptions of cholesterol-fighting statins.

The guidelines announced in November by the American College of Cardiology and the American Heart Association advise that people with 7.5% or higher risk for heart attack be prescribed statins as against the existing guideline of a 20% or higher risk rate. This is expected to double statin usage in the US from the existing 36 million.

A representative of Dr Reddy's Laboratories, India's second-largest drugmaker, said the company is "conscious of this guidance (new statin usage guidelines) and watching the dissemination of any changes in the practice by various physicians."

The Hyderabad-based company reported Rs 3,785 crore of sales in the North American market in 2012-13 HSBC Securities and Capital Markets analyst Girish Bakhru said that among Indian generics makers, Lupin, Dr Reddy's and Cadila are best positioned to gain from increased statins use. "We expect higher future use for Atorvastatin, Simvastatin, Crestor and other smaller statins."

Cholesterol-reducing drugs worth nearly $15 billion (Rs 92,000 crore) were sold in the US in the year to September 2013, Bakhru wrote in his latest report. Statins accounted for nearly half of that amount. Statins come in various flavours such as simvastatin, lovastatin, pravastatin and atorvastatin depending on dosage.

For example, a smaller dose of atorvastatin is equal to a larger dose of simvastatin. According to the latest IMS Health data on anti-cholesterol medicines, Indian companies have about a 43% share of the market for statins.

India exported medicines worth $14.5 billion in 2012-13, of which exports to North America were over $4 billion.

Lupin spokesperson Shamsher Gorawara said, "The new guidelines also promote the use of statins as frontline therapy in managing cholesterol given better risk-benefit ratio with lowest number of safety issues as compared to other therapies. As such one might see a bigger market for statins in the US."

Lupin earned 39% of its Rs 2,668 crore revenue from the America during the second quarter of this fiscal year.

Source: *The Economic Times, 27th December 2013*

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U.K. Health Regulator Initiates Recall of 5 Wockhardt Drugs

British health regulator Medicines and Healthcare Products Regulatory Agency (MHRA), on Thursday, initiated recall of five prescription medicines of Wockhardt, following manufacturing deficiencies identified during an inspection of the company's site in Chikalthana in Maharashtra.

This follows a precautionary recall by Wockhardt, which is asking retail outlets to return five over-the-counter medicines, the MHRA said in a statement.

"Ten prescription-only medicines can continue to be made at the Chikalthana site, and can still be supplied to patients in the U.K.," the MHRA added.

This is because, due to concerns over the continuity of supply, the benefits to patients of continuing to take these medicines outweigh the risk from any quality concerns with the medicine, the MHRA said.

When contacted Wockhardt Chairman Habil Khorakiwala told PTI: "We are moving forward to comply with MHRA requirements and we should be doing it quite soon."

Wockhardt in a filing to BSE said: "The agency (MHRA) has issued a drug alert for recall of certain products, one time impact of which is expected to be approximately one million pounds." The MHRA said the medicines affected by the recall are in most cases available from alternative manufacturers.

Source: *The Hindu, 18th October 2013*

Bayer Challenges IPAB's Order on Cancer Drug

German drug major Bayer AG has challenged the Intellectual Property Appellate Board's (IPAB's) order of compulsory licence issued to domestic pharmaceutical company Natco Pharma in the Bombay High Court and has sought the court's intervention to protect its rights over patented cancer drug Nexavar.

"We introduce the product after years of research and investment, while companies like Natco merely copy and manufacture the product," said Ravi Kadam, senior counsel who is representing German pharmaceutical company in the case. "They (domestic companies) are making money while Bayer gets 7%, as royalty from the Indian pharma company."

The division bench comprising Justice SJ Vazifdar and Justice KR Sriram adjourned the hearing to October 29. Earlier in March 2013, IPAB directed the Hyderabad-based Natco Pharma (NPL) to continue the manufacture and sale of the generic version of Nexavar, Bayer's kidney cancer drug.

"We strongly disagree with the conclusions of IPAB," said Bayer spokesperson to ET's email query. "Bayer is committed to protecting its patent for Nexavar. We will rigorously continue to defend our intellectual property rights within the Indian legal system. The challenges faced by the Indian healthcare system have little or nothing to do with patents on pharmaceutical products as all products on India's essential drug list are not patented. The order of IPAB weakens the international patent system and endangers pharmaceutical research." A phone call and email to Natco Pharma did not elicit any reply.

In March last year, Natco Pharma was granted first ever compulsory licence to sell the cancer drug at Rs 8,800 for a month's therapy, and pay 7% royalty to Bayer on the sales. This was challenged by the German pharma company.

Bayer's same anticancer drug is priced at Rs 2.8 lakh a month.

"India didn't had any patent regime till 2005 and it's still new to us," said Sarabjit Kaur Nangra, vice president - research at Mumbai based brokerage firm Angel Broking who tracks pharmaceutical sector. "We may witness some more case in the sector before domestic company understands it fully."

Apart from Bayer, another European pharma major, Novartis also had to face the blow when the Supreme Court rejected the company's plea regarding patent application for Swiss company's anticancer drug Glivec in April 2013.

Source: *The Economic Times, 12th October 2013*

Pharma's David & Goliath in Race to Produce Insulin Pill

An insulin pill, long desired by diabetes doctors and patients but abandoned as not physically viable, could be available by the end of this decade as a tiny Israeli company races a Danish pharmaceutical giant to be first with what could be a multibillion-dollar product.

In the pharma industry's equivalent of a David and Goliath story, the companies at the forefront are Novo Nordisk, the world's largest seller of insulin products with a market value of about $74 billion, and Oramed Pharmaceuticals Inc, with a market value of only $50 million and headquartered in Jerusalem, where the biblical David held court.

The concept of oral insulin as a way to relieve people with type 1 diabetes of several daily injections has been around since the 1930s. It was left for dead because as a protein composed of amino acids, insulin is destroyed by enzymes in the digestive system before it can do any good.

While skepticism over a viable insulin pill remains high, Novo and Oramed believe they have come up with solutions that will allow enough insulin to survive the onslaught of digestive juices.

"We've built technologies and we've seen from studies in animals and early human trials that this may not be as impossible as decades of research had indicated previously," said Peter Kurtzhals, Novo's head of diabetes research.

If all goes well, Novo believes its oral insulin could be available by the end of this decade or early next decade.

Oramed's program is ahead of Novo's. It has begun enrolling patients in Phase II, or midstage, clinical trials, while Novo has yet to begin Phase II testing.

The brains behind Oramed's oral insulin is the chief executive's mother, Miriam Kidron, who laid the groundwork with years of diabetes research at Hadassah-Hebrew University Medical Center. "She's the chief scientist. I just went for the ride to do the business side," said Oramed CEO Nadav Kidron.

"My mother said it could be commercial but Hadassah won't be able to fund it," Kidron recalled. "I took the IP from Hadassah and started Oramed. Since then, we've been moving it forward."

Regardless of who wins the race, Kidron said, "there must be an oral insulin. This is going to be a huge market." He sees the market potential to be at least $7 billion a year.

Novo said this week the global market for diabetes tablets could be worth more than $18 billion a year.

That is because the focus for oral insulin has shifted to the ballooning health crisis of type 2 diabetes, a progressive disease often caused by

obesity. An estimated 90 to 95 percent of the more than 370 million people living with diabetes worldwide suffer from type 2, according to the International Diabetes Federation. It projects that could climb to 552 million by 2030.

GBI Research forecast the global market for type 2 diabetes treatments reaching nearly $40 billion by 2019.

"Even though there are other anti-diabetic agents and more coming in, ultimately all (type 2) patients with diabetes, if they live long enough, will need insulin," said Novo's Kurtzhals.

There is still a long way to go for Nova or Oramed to receive regulatory approval. The companies must prove the worth of their oral preparations with large clinical trials and demonstrate no heart problems or other major side effects.

Other than injections, no other insulin preparations have been shown to be satisfactorily safe and effective, doctors said. Past failures of alternative delivery systems include Pfizer Inc's abandonment in 2007 of its inhaled insulin product.

"I'm not going to hold my breath on this one," said Dr. Robert Ratner, chief science and medical officer for the American Diabetes Association (ADA).

"It would be an important contribution to the therapeutic armamentarium. But there are still great limitations in our ability to get the insulin absorbed and control how much insulin gets absorbed," Ratner said.

Other treatments being tried include nasal spray and a skin patch, which lack some of the potential advantages of an oral insulin.

A MORE NATURAL APPROACH

Insulin injections were introduced commercially as a life-saving treatment for diabetes in 1923 by Eli Lilly and Co. Novo has also sold insulin products for some 90 years.

While insulin is naturally produced in the pancreas and then goes to the liver, injected insulin circulates throughout the body before it gets there. The main attractiveness of an insulin pill, if it works, is that any absorbed insulin would go directly to the liver from the digestive tract.

"It is a much more natural physiological approach," said Dr. Joel Zonszein, director of the Clinical Diabetes Center at Montefiore Medical Center in New York.

Some doctors believe high levels of insulin circulating through the rest of the body may increase health risks.

Since the digestive system can break down insulin in a matter of seconds, both Novo and Oramed's approaches for their insulin pills involve protective coatings and molecular tweaks or added ingredients to help enough insulin be absorbed to provide effective glycemic control. That involves giving large enough doses of insulin so that some 90 percent can be destroyed without sacrificing efficacy.

Novo believes it has designed a more stable molecule than natural insulin that can slow the time of degradation to minutes. "And if you can do that, maybe it's sufficient time for absorption to take place," Kurtzhals said.

"Risk is still high for this type of project. But the chance of success has gone up quite dramatically in our own minds compared to what it was originally," he said.

Oramed has introduced a protease inhibitor and another tweak designed to protect and enhance absorption of its oral insulin.

Kidron sees oral insulin as an opportunity to save billions of dollars in healthcare costs by helping

to delay the myriad complications associated with type 2 diabetes.

"If we give insulin earlier on, we're going to give the pancreas a rest," Kidron explained. "We could reduce the complications, such as blindness and amputations."

He likens earlier treatment with an insulin pill to Pfizer's Lipitor, which became the most profitable drug in history by preventing serious heart problems.

Dr. Jason Gaglia, a top researcher at Harvard Medical School's Joslin Diabetes Center, said an oral insulin could be used to better control overnight blood sugar.

"If you could give it in an oral pill that is just hitting the liver, it would be wonderful," he said. "If people take this pill at dinner time, they're not going to have this excess glucose production overnight and it will be really good for getting those morning blood sugars down."

INSULIN STIGMA

Persuading patients to take insulin earlier in their disease could take some work, however. Some doctors now see a stigma surrounding the need for insulin - rather than needles, which have become much smaller and less painful - as a possible impediment to its acceptance by those with type 2 diabetes.

Patients may see insulin as an indication they are sicker than they perceive themselves to be, or associate it with a relative who got insulin late in the disease only to see their health deteriorate, doctors said.

"We need to do some education to convince people that insulin is a therapy like any other and it's very effective," said Dr. Elizabeth Seaquist, a member of the Endocrine Society who is in line to become a future ADA president.

The riskiness of the project and the number of years it will take to come to fruition is likely a reason Oramed's market value remains relatively small. The shares are trading for just over $6 and the CEO is the largest shareholder.

The company, which is also developing oral versions of other injectable drugs, plans to take its insulin through Phase II testing and then find a partner with deep pockets to conduct large, expensive Phase III trials and market the drug.

Kidron see no shortage of potential partners among Japanese drugmakers, U.S. companies with diabetes sales forces, or even Novo Nordisk - a scenario in which Goliath could simply buy David's slingshot.

"Novo is in a different league from anyone else out there," Kidron says with admiration. "I look up to them."

Source: *The Economic Times, 11th October 2013*

Trials Successful, Malaria Vaccine Likely in 2 Years

A vaccine against malaria may become a reality in two years after results of clinical trials, announced on Tuesday, showed it had effectively protected infants and young children up to 18 months after vaccination.

The results of the phase -III trial announced by British pharmaceutical company, Glaxo SmithKline (GSK), demonstrated the vaccine - RTS,S - reduces malaria cases to almost half (46%) in children (aged 5-17 months at first vaccination) and to around a quarter in infants (aged 6-12 weeks at first vaccination) over an 18-month follow-up period. The company plans to submit next year a regulatory application to the European Medicines Agency(EMA) which can clear the world's first vaccine against a parasitic disease by 2015.

RTS,S triggers the immune system to defend against plasmodium falciparum, the malaria parasite carried by mosquitoes, when it first

enters the human host's bloodstream and when the parasite infects liver cells. It is designed to prevent the parasite from infecting, maturing and multiplying in the liver, after which the parasite would re-enter the bloodstream, leading to disease symptoms.

"While we have seen some decline in vaccine efficacy over time, the sheer number of children affected by malaria means that the number of cases the vaccine can help prevent is impressive," said GSK chief executive Andrew Witty. The company vowed to sell the vaccine at cost price plus 5% which, it said, would fund further research in tropical diseases. The company said RTS,S continued to display an "acceptable safety and tolerability profile" during the follow-up period.

Source: *Times of India, 9th October 2013*

HC Restrains Wockhardt From Manufacturing and Selling Proxyvon

The Madras High Court has restrained pharma major Wockhardt Ltd., from manufacturing and selling 'Dextyropropoxyphene' (DPP) and the formulations containing it till the disposal of two writ petitions.

Justice K.K. Sasidharan passed the interim order on petitions by the company and a distributor challenging a notification of May 23 this year of the Health and Family Welfare department suspending the manufacture for sale and distribution of the drug and the formulations containing it for human use.

The company-manufactured 'Dextyropropoxyphene Napsylate' and it was sold under the brand names "Proxyvon" and "Spasmo-Proxyvon" which were widely used analgesic and antipyretic drug. They were used primarily for relief of high fever, headache, extremely acute pain that arose out of cancer and other similar oncological conditions or acute pain due to extreme orthopaedic conditions and complex fractures.

The sale of "Spasmo-Proxyvon" alone fetched Rs. 168 crore in 2012-13 financial year. The turnover of 'Proxyvon' was around Rs. 100 crore per year. The deliberations of the meeting of the Drugs Technical Advisory Board in October 2011 resulted in the impugned notification.

The manufacturer and the distributor sought an interim stay of all further proceedings pursuant to the May 2013 notification. The pharmaceutical company contended that the notification did not contain any valid reason to suspend the drug sale. Inputs like suggestions or representations from manufacturers' association and other experts were not taken before suspending the drug. The Deputy Drugs Controller, Chennai, contended that DPP was withdrawn from the US market in September 2010 at the instance of the United States Food and Drugs Administration on the ground that the drug could cause serious toxicity to the heart even when used in therapeutic doses. The manufacture and sale of DPP in India was considered by an expert team which wanted to conduct further study in the matter. In the meantime, to stop further manufacture and sale of DPP and formulations containing it for human use, the impugned notification was issued. Mr. Justice Sasidharan said experts had taken a decision to suspend the drug for the time being till a close study was conducted regarding its adverse effect on human beings. The counter showed that the suspension was only a temporary measure pending final decision to be taken by the government after extensive study. Therefore, it was clear that the government was yet to take a decision to ban the drug permanently. The Judge also restrained the distributor from marketing the drugs. The other directions included that in view of the direction to take inventory of the drugs and to keep it separately no penal action should be taken on account of possession of the drug.

If it was found that the manufacturer possessed the suspended drug or its preparations other than the quantity already disclosed, it was open to the Drugs Controller to seize the drug and take action. Mr. Justice Sasisdharan made it clear that the directions would be in force till the disposal of the writ petitions.

Source: *The Hindu, 6th October 2013*

Pharmacists Fast, Want Posts Filled

The protestors said that of the 3,700 sanctioned posts, 400 were empty

Scores of pharmacists went on a day-long hunger strike on Thursday, demanding that vacancies be filled up in government hospitals.

The pharmacists, who came from as far as Theni, Perambalur, Salem and Tuticorin, said that of the 3,700 sanctioned posts across government medical institutions in the State, 400 were vacant. Of these, 300 are in primary health centres.

The protestors want the government to appoint one pharmacist for every 100 outpatients and every 75 inpatients in a hospital.

"The long queue for medicines outside pharmacies in government hospitals can be shortened by opening more counters and appointing pharmacists," said the association's president V. Govindarajan.

"According to the Drugs and Pharmacists Act of 1948, only pharmacists can handle drugs. There are 10,000 qualified diploma-holders in the State who can be offered these posts," he added.

The pharmacists say that in many hospitals, the person who handles drugs is an administrative head without any understanding of drugs or their composition.

In a meeting held in 2010 in which the then health secretary, the directors of medical education, public health, medical services and ESI hospitals participated, it was decided to appoint a chief pharmacist at every hospital with 30 beds. Though the government issued an order to this effect, it has not yet been implemented, Mr. Govindarajan said.

The pharmacists also want their work time in PHCs to coincide with that of the doctor. At present, they work from 8 a.m. to 5 p.m. whereas the doctor works from 9 a.m. to 4 p.m. "Only if there is a doctor, can we do our job," said A. Balamurugan, the strike's organising secretary.

Source: *The Hindu, 4th October 2013*

USFDA Observes Quality Violations at Wockhardt's Plant

The US Food and Drug Administration (FDA) has made serious observations on Wockhardt's manufacturing plant at Chikalthana, citing major quality violations. The filing marks the second time this year that the US regulator noted violations of good manufacturing practices at a Wockhardt facility.

In July this year, Wockhardt's plant at Waluj came under the USFDA scanner, with the regulator issuing a warning letter as well as an import alert, banning drugs from the facility.

The Wockhardt scrip ended nearly 5% lower at Rs 550 on the BSE by close of Friday's trade.

The Chikalthana document , known as FDA Form 483, listed 16 observations about Wockhardt's factory in Chikalthana, on serious concerns about quality control at the plant. While it is not known whether the USFDA will impose an import alert for this plant, analysts say that the observations are serious.

When USFDA inspectors visited in July this facility, which produces generic copies of the

heart tablet Toprol-XL , they reportedly found urine spilling over open drains, soiled uniforms and mould growing in a raw-material storage area. Wockhardt controls about 26% of the US market for that pill.

A Wockhardt spokesperson said: "We have responded to the observations made by the USFDA post inspection of the Chikalthana facility and a response from them is awaited" . The facility was intended to serve as a production backup after the USFDA's action in July against the Waluj plant, near Aurangabad.

Source: *The Times of India, 28th September 2013*

USFDA's New India Chief Eager to 'Scale Everest'

The US Food and Drug Administration's new India chief, Altaf Ahmed Lal says he will interact with the Indian industry and regulators to discuss preventive measures to avoid manufacturing lapses that have caught the attention of the US authorities.

Currently on a tour to the US, Lal blogged on Wednesday that a colleague of his likens his new role (as FDA's India chief) to scaling Mount Everest. "But I am fond of trekking and climbing," he quips in the blog.

ET reported last month the striking spike in the frequency of US FDA's regulatory action in India during last three-four months. India-based drug manufacturing sites, including those belonging to multinationals faced a deluge of warning letters from the US drug safety office.

Lal, who took over as director, USFDA India Office in June, states that over next two years he would like to hold open transparent discussion with industry and regulators about preventive measures that should be taken to avoid violations during manufacturing processes.

"I want a manufacturer to ask - and be able to answer - the questions, why are we failing inspections? And what specific controls do we still need to put into place on a 24/7 basis so that on the next FDA inspection we will pass?" he wrote in the blog.

An ET analysis last month showed that India-based drug manufacturing sites, including those of multinationals accounted for over 60% of all such warning letters sent out globally by the US drug safety office Centre for Drug Evaluation and Research (CDER) in the past three months.

The report showed that the current rate of getting slapped with one red flag every fortnight over the last three months strikes as remarkably high when seen against the warnings letters that drug facilities in this country received over last three years.

For instance, plants located in India received about 10 warning letters from the CDER between 2010 and 2012, making for less than a tenth of over 130 warning letters that the US drug safety office sent out in the last three and half years. Besides domestic firms Wockhardt and RPG Lifesciences, Promed and Posh Chemicals, India-based facilities of foreign firms - US-headquartered Hospira and Germany-based Fresenius Kabi - also drew the USFDA's ire during the period. Since last month, two more warning letters have been issued to Indian drug making sites-of Bengaluru headquartered Strides Arcolab and API player Aarati Drugs. At least in three of these cases, FDA has alleged data falsification.

Ranbaxy's latest state of art facility at Mohali, on which the company had pinned hopes to overcome its prolonged regulatory troubles, has attracted an import alert, which bars exports from the plant to US. The rise in detection of fault is partly because US FDA is increasing its activities and manpower in India.

Lal says his task in India is cut out; "to help industry and regulators understand that protecting the quality, safety and effectiveness of every product is essential, to conduct prompt and thorough inspections, when needed, of firms producing products for U.S. export and to work closely with FDA's Indian counterparts".

He considers his new job in India, a challenge and an adventure, he is eager to be a part of.

Source: *The Economic Times, 27th September 2013*

Rationale of Combination Drugs May Have to Be Explained For Getting Marketing Nod

Pharma firms need to explain the medical rationale for combination drugs while seeking marketing approval for them, an expert panel set up by the government has recommended.

This move is intended to get rid of irrational combination drugs which have flooded the domestic market today. Combination drugs comprise over 46% of the 70,000-crore domestic drug market.

Drugmakers would have to show why an ingredient needs to be combined with another while seeking clearance to sell the drug. "If the actives (main raw materials) in an FDC (fixed dose combination drug) are intended to relieve different symptoms of a disease state, it is a prerequisite that these symptoms commonly occur simultaneously," said the expert panel headed by Professor CK Kokate.

Pharma firms must be able to prove that two drugs when combined increase efficacy of the treatment vis-a-vis taking the drugs separately. To gain marketing approval for a combination drug, the expert panel suggests, the drug firm has to prove that the proposed combination medicine is either reducing side-effects, or reducing the dose or cutting price or improving compliance on part of patient or reducing incidence of resistance development, compared to existing therapies or would help in easy distribution, the panel has recommended.

Besides, the drugmaker may have to furnish possible risks and disadvantages a combination drug may pose.

The committee, constituted early this year, recommended that combination drugs be classified into four categories and different clearance norms be specified for each. Those in which one or more ingredient has not been approved for use in India, those which have not been marketed in India but its constituents have been approved and marketed individually in the country form the first two categories, and stricter marketing clearance routes have been proposed for them.

Relatively easier norms are recommended for other categories of combination drugs, such as when the drug in question is already being marketed in India but a pharma company proposes a minor tweak (changing the ratio of ingredients, for example) and in case of drugs which are already being marketed in the country.

The government came under pressure to streamline the approval of fixed dose combination drugs after a Parliamentary Standing Committee pointed out last year that many 'unauthorised' combination drugs, which have been not tested for safety and efficacy, are being openly sold in the market. The panel also said that many of these drugs do not even have mandatory clearance from the Drug Controller General of India's office, and have launched in the market by getting approval from various state drug regulators.

Source: *The Economic Times, 25th September 2013*

Supply Essential Drugs: Govt Tells Companies, Stockists

Perturbed by reports of shortage of essential medicines on retail shelves after the implementation of new pharma policy, the government has sent out a sharp message to drug companies and trade channels to ensure their availability across the country. Supplies of widely used medicines such as pain relievers paracetamol and diclofenac, treatment for worms albendazole and those used in chronic ailments like cholesterol-lowering drug atorvastatin,diabetes drug metformin and blood pressure drug enalapril have been affected.

The drug pricing regulator, NPPA (National Pharmaceutical Pricing Authority), in a strongly worded communication to pharma companies and distribution channels, has warned that the Essential Commodities Act may be invoked against those who disrupt the supply and distribution of essential medicines.

The supply of certain crucial medicines used in tuberculosis and leprosy treatment and injections oxytocin, metylergometrine and amikacin used in surgeries and deliveries have also been disrupted over the last couple of months, industry sources told TOI (see chart).

The NPPA, citing the Drug Price Control Order (DPCO) 2013, has said in the letter that no drug formulation can be sold to a consumer at a price exceeding the one notified by the government or the one printed on the medicine pack. The government notified in July ceiling prices of certain medicines which are part of the National List of Essential Medicines. Citing Para 28 of the DPCO 2013, the NPPA communication said that no manufacturer can refuse to sell a drug to a distributor while no distributor can withhold the sale of a drug to a consumer planning to purchase the medicine.

Representation from the industry association and reports received indicate that there is a disruption in supplies of key medicines due to withholding sale of certain medicines by stockists and retailers protesting against the trade margins, the letter said.

Since the implementation of the new pharma policy, a tussle has been on between pharma companies and trade channels over margins, with stockists reducing their orders leading to scarcity of widely prescribed medication like painkillers, anti-infectives, cardiac drugs and antibiotics. Supplies of essential medicines have been particularly disrupted in Gujarat, Karnataka, Tamil Nadu, West Bengal and Jharkhand.

Major companies like Cipla, Mankind Pharma, FDC and Torrent have given in to the demand of higher trade margins, hoping to end the stalemate between the industry and chemists. Drug major Cipla and Mankind Pharma increased trade margins - 10% to stockists and 20% to retailers - on the price-controlled basket of drugs, as against the earlier offered 8% and 16%, respectively. Others like Torrent and Eris Life Sciences are doling out a 5% "special discount" on these medicines.

The DPCO 2013 stipulates a trade margin of 16% to retailers while to wholesalers the industry offers a trade margin of 8% on price-controlled drugs, continuing with the earlier practice. For medicines out of price control, trade channels continue to get margins of 10% and 20% as earlier.

COUNTERING CRUNCH

Drugs	Formulation/ brands	Duration of unavailability
Oxytocin inj	Syntocinon	July, Aug & Sept
Methyl-ergometrine inj	Methergin	July, Aug & Sept
Metoprolol tab	Cardibeta XR 12.5	Aug & Sept
Metformin 500mg	Riomet OD 500mg	Aug & Sept
Atorvastatin 5, 10, 20	Storvas tablets	Aug & Sept
Albendazole	Bandy tablets	Aug & Sept
Clopidogrel 75mg tab	Plavix	Aug (rationing in Sept)
Paracetamol	T 98 tablets	Aug & Sept
Amikacin inj		Aug & Sept
Diclofenac 50mg tab		July, Aug & Sept

Source: *The Times of India, 24th September 2013*

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The Sad Story of A Good Vaccine

Lax monitoring, poor public engagement and inadequate training to vaccinators have dealt a serious blow to the crucial pentavalent immunisation programme

The Pentavalent vaccine, the Ministry of Health and Family Welfare's latest addition to the immunisation programme, has run into a storm. The Supreme Court has sent a notice to the Ministry asking why the vaccine should not be banned in the country.

The vaccine is no stranger to controversy. A mix of five vaccines to fight childhood diseases like diphtheria, pertussis, tetanus, Hepatitis B, pneumonia and meningitis caused by Haemophilus influenzae Type B, its roll-out in nine States has been opposed after infant deaths were reported post vaccination.

Adverse events

So far, 82.72 lakh doses have been administered in the country and 29 serious cases of Adverse Events Following Immunization (AEFI) have occurred following immunisation. Kerala reported 15 deaths; of these, six children had co-morbidity such as congenital heart disease, eight were Sudden Infant Death Syndrome (SID), where the cause of death is unknown, and one infant probably died due to the vaccine. Haryana reported five deaths, Tamil Nadu four, Karnataka three and Gujarat and Jammu and Kashmir one each.

"There is no clear evidence that these deaths were related to the vaccine," says Dr Ajay Khera, Deputy Commissioner, Child Health and Immunisation. "All AEFI cases were investigated and the findings of the team of experts ruled out any linkage of cause of these deaths with the vaccine." He also says information of causality is limited since autopsies are not being permitted by many families.

But there are concerns, says a senior paediatrician. "Out of 15 deaths, only six were clearly established to be not related to the vaccine. That is not good enough in a vaccination programme. It is not a question of safety alone but also of the delivery system. Families need answers. The follow-up to these deaths needs to be more meticulous to understand what caused these deaths."

Other Asian experiences

The vaccine was introduced in India after intense deliberations between the Health Ministry and the National Technical Advisory Group on Immunisation (NTAGI). Its report states that the vaccine is safe and recommended that it be introduced in all States to combat a large but preventable burden of disease.

Vietnam, Sri Lanka, Pakistan and Bhutan faced a similar predicament when adverse events were reported following which the vaccine was suspended. After it was found that there was no obvious link between AEFIs and the vaccine, it was reintroduced in the immunisation programmes. Indonesia has done the same recently.

Dr. Cyrus S. Poonawalla, Chairman, Poonawalla Group, who owns the Serum Institute that manufactures the vaccine, contests these charges. He says: "India is not the only country to use pentavalent vaccine ... 170 countries have introduced the vaccine. Not a single child has died due to the administration of the vaccine anywhere in the world. Each container has 10 doses and if there was something wrong with the vaccine then all 10 children who received the vaccine should have shown adverse reactions; but nine others were not affected. This is clear proof that the vaccine is all right. In most of the cases, there are other causes, say the injection delivered in unhygienic environment or there are underlying medical conditions, which are not identified."

Dr. Yogesh Jain of Jan Swasthya Sahyog, who filed the petition in the Supreme Court demanding that the pentavalent vaccine be banned in India says, "We are not against vaccines, it is an important public health tool. What prompted us to file the petition was the death of children within 24 hours of administering the vaccine. We wanted to know the cause of death of these children but the report is not available. Also, the effects of administering a combination of too many vaccines need to investigated and shared with us as well."

According to experts, when a new vaccine is introduced, it is imperative that the procedures that merit caution are followed. It is also mandatory that all AEFI should be looked into and then reported to the Drug Controller General of India (DCGI). But this practice has not been followed. He says, "Is there an acceptable rate of death for vaccines? When a child has a congenital heart disease, is there a need to vaccinate the child? These are programmatic errors that need to be addressed. We filed the petition because we believe that judicial oversight is necessary in this case."

Vaccines are known to be safe and one of the best preventive tools to protect children from disease. In India, nearly three-and-a-half lakh children die of pneumonia and meningitis every year and the best way to save these lives is a vaccine.

Dr. N.K. Ganguly, Advisor, Translational Health Science and Technology Institute (THSTI), says that the benefits of the vaccine outweighs the risks. "The system has been strengthened so a larger number of serious adverse events and deaths are being reported. Every case must be monitored after immunisation. In case deaths occur, autopsies must be done to establish the cause of death. Children with co-morbidity should be provided care and with better follow-up of every child. It is an injectable vaccine, so the delivery mechanism, maintenance of cold chain must also be monitored to ensure better case management," he adds.

Currently, the government's AEFI guidelines do emphasise post-vaccination monitoring and protocols for examination of AEFI cases but they do not have any instructions on how health workers and local medical officers should track and monitor the pre-vaccination medical status of children and the appropriate steps that should taken in cases underlying morbidity.

Model worth considering

Immunisation is done by health-care providers like auxiliary nurse midwives, who are often not trained enough to recognise clinical symptoms prior to administering the vaccine and the ability to provide support in case of adverse events. Vaccinators need to be well trained in the importance of identifying underlying conditions of the child before vaccinating, make parents understand the risks of vaccinating in case of any underlying condition and ensure post-vaccination care if there is any event of crying, fever and convulsions.

In Christian Medical College and Hospital, Vellore, around 31,200 infants receive the vaccine annually. So far no deaths have been reported. Prior to immunisation, every child's medical history is evaluated in detail. Post vaccination, the child is followed up closely to address any side effects or adverse events, reducing any risk to the child. In short, an ideal delivery model that can prevent or reduce infant deaths and morbidity and build confidence in the vaccine.

In Sri Lanka, where it was found that infant deaths after immunisation were due to congenital heart disease, infants are now immunised under medical supervision, especially if there are underlying health conditions.

Paediatricians say that this should be made mandatory in India as well.

Communication

Another loophole in the programme is poor public engagement. It is a tough ask for parents to reconcile with the death of their newborn baby, who was apparently healthy before the vaccine was delivered. With growing awareness about the value of vaccines and rising demand for better health for their children, families place their trust in the system. But if a child dies and the cause of death is unknown, parents lose faith in the system and the product, no matter how safe it may be. It was only after medical experts bulldozed the government, that some answers are emerging.

For the 27 million children born every year, each life counts. So far, millions of lives have been saved through vaccination, but for the pentavalent to be truly accepted, it is essential that the government is more transparent and rapid in its response following adverse events.

If the public health system provides quality immunisation services and ideal case management AEFI, cases can be minimised. This is the government's own promise, which it needs to keep for children to remain healthy and safe.

(Mohuya Chaudhuri is an independent journalist. She was formerly health editor at NDTV. E-mail: mohuya.chaudhuri@gmail.com)

Source: *The Hindu, 24th September 2013*

USFDA Finds Data Fudging at USV's Labs

The United States Food and Drug Administration (USFDA) has accused Mumbai-based drug maker USV of fudging data, adding to the list of domestic companies such as Ranbaxy Labs and Wockhardt that have come under the drug regulator's scanner.

After an inspection of USV's Mumbai laboratory in June, the US drug regulator said the company's "drug product test method validation data is falsified", according to documents reviewed by ET.

USV, one of India's top 20 drugmakers, is the third manufacturer after Mumbai-based Wockhardt and Hyderabad-based Posh Chemicals to be hauled up by the USFDA for allegedly tampering with data in the past three months. However, the most high-profile case of "systemic data falsification" from India remains Ranbaxy's.

While the USFDA sent out letters warning Ranbaxy, Wockhardt and Posh after inspecting their facilities, USV has not yet received a warning letter from the US regulator even as lapses have been communicated in the form of observations. Another difference in USV's case is that the US regulator found violations at this company's testing labs while in the other three cases it found the manufacturing facilities at fault.

"Based on our findings and analyst's own admittance that he modified analytical balance weight print-outs, there is no assurance that the sample and the standard weight values...are representative of the actual weights," the USFDA investigators told USV's managing director Prashant Tewari in an inspectional observation in June. "Analytical balance clocks are modified in order to create falsified weight print-outs that appear to be printed at the time of sample weighing," the investigators said in their damning observations, as per the papers reviewed by ET.

The US regulator has also reprimanded USV for not training its staff in current good manufacturing practices. Admitting that the company had received adverse inspectional observations from the USFDA on its testing lab,

USV's COO Debabrata Gupta told ET that the company expected a successful resolution soon."We have taken suitable corrective actions in consultation with US-based consultants and have responded to USFDA appropriately on the Form 483 observations on July 1, 2013," Gupta said.

Source: *The Economic Times, 23rd September 2013*

Health Experts Call for Rational Use of Antibiotics

Over the years, Ganesh, a city-based pharmacist has observed just how his customers' know-how on self-medication has evolved.

"Earlier, people would come to pharmacies and ask for Erythromycin for a throat infection. Today, they ask for a stronger antibiotic, Azithromycin. Since antibiotics are available over the counter and are fast-acting, people take them for anything - even a common cold or fever," he said.

Experts say the city's continuing indiscriminate use of antibiotics is a cause for concern, especially as an increasing number of antibiotic-resistant cases are being reported.

"People take antibiotics for ordinary fever or flu-like symptoms, which can be self-limiting. At times, diarrhoea too, can be self-limiting and oral re-hydration solutions are enough to treat it. But very often, anti-diarrhoeal drugs are prescribed. The use of antibiotics is rampant here, and there is no standard protocol for prescribing them. If giving antibiotics over-the-counter is wrong, then prescribing these medicines without knowing the actual cause of the illness - viral or bacterial - is also wrong," said S. Elango, president of the Indian Public Health Association, Tamil Nadu branch.

The Central Drugs Standard Control Organisation has, time and again, laid emphasis on the rational use of antibiotics. In a note, it said that development and spread of antimicrobial resistance is commonly due to overuse, misuse and indiscriminate use of antimicrobials by doctors, nurses and pharmacists and self-medication by patients.

According to the note, an estimated 70 to 80 per cent of prescriptions for antibiotics are probably unnecessary. "But even more than the number of antibiotics prescribed is the amount bought by patients over the counter. Patients now know the names of medicines and straightaway buy them without consulting a doctor. In many cases, they produce an old prescription and get the antibiotics without even knowing the cause of their own illness," said a government doctor.

To promote the rational use of antibiotics, the Indian Medical Association (IMA), Tamil Nadu along with other professional health bodies has approached the State health department to prepare a district-level Antibiogram - a test for the sensitivity of a bacterial strain to different antibiotics.

"The sensitivity of bacteria to drugs varies from place to place, as they constantly undergo mutations/genetic changes. It is better to identify common bacterial strains at a particular place as well as drugs to which they are sensitive. Hospital-level antibiotic policies can be formulated based on this antibiogram," explained J.A. Jayalal, honorary State secretary of IMA-TN.

The practice of taking antibiotics for any and every ailment has seeped into villages too, he said.

he Centre's move to ban over-the-counter sales of 92 drugs, including antibiotics, will go a long way to curbing this practice, he added.

Dr. Elango said multi-drug resistant tuberculosis has become a major public health concern and was caused mainly because patients bought over-the-counter drugs for a cough without being tested for or even realising they had TB.

"There should be a flowchart on when to prescribe antibiotics and what type, say for fevers with cough, fevers with rash, diarrhoea and eye infections," he said.

N. Raj Ganesh, State president of Tamil Nadu Government Pharmacists' Association said the government should first survey the sale of antibiotics at pharmacies for a certain period.

Source: *The Hindu, 20th September 2013*

USFDA Found Suspected Hair, Oil In Ranbaxy Tablets

Tablets embedded with 'black fibre' that was suspected to be hair from an employee's arm, 'black spots' of oil from machines in tablets and absence of running water in toilets were some observations made by USFDA that has banned import of drugs made at Ranbaxy's Mohali unit.

According to USFDA documents sent to Ranbaxy's Mohali plant head after a series of inspections in 2011 and 2012, the US health regulator made 11 observations citing various violations of current good manufacturing practices (cGMP).

"There is a failure to thoroughly review any unexplained discrepancy in the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed," the USFDA said.

Citing an example, the USFDA observed that in August 2012 it was concluded that a "black fibre embedded in a tablet" was likely either "tape remnants on the nozzle head of the machine or a hair from an employee's arm that could be exposed on loading the machine".

"The firm did not conduct any analysis of the fibre to support these root causes. Further, a plan to evaluate whether the corrective actions of trimming the tape and implementing longer gloves for employees were effective was not established," it added.

Comments from Ranbaxy Laboratories could not be obtained as a query remained unanswered. Earlier, it had however said it "will review the details and will continue to fully cooperate with the US FDA and take all necessary steps to resolve the concerns at the earliest".

Pointing out further cGMP violations, the USFDA said in response to the presence of black spots observed during tablet compression, "the investigation did not include chemical analysis of the tablet or contaminated tablets to support the absence of contamination and the root cause, which was determined to have originated from oil in the compression machine."

The USFDA also pointed out the lack of hygiene in the toilet complexes of the plant.

"During the course of the inspection, the toilet facility adjoining change room of the raw material storage area did not have running water for hand washing and toilet flushing," it said.

Stating that washing and toilet facilities lacked hot and cold water, USFDA further said: "Additionally, there are no procedures to direct employees to wash hands with soap and water after toilet use and prior to gowning..."

Source: *The Times of India, 19th September 2013*

Clinical Trials in India to Get Stricter

In an attempt to bring about reforms in drug regulation and clinical trials, a six-member expert panel constituted by the ministry of health and family welfare has said that in future, these trials can only be carried out in accredited centres. Also, the principal investigator and ethics committee of the institute where the trial is being done, should also be accredited. Only then will trials be approved.

"While some of the recommendations can be implemented within two months after consultations, others will require an amendment of rules," says a senior health ministry official. "The government will ensure that clinical trials are done legally and the safety of participants is adhered to."

Dr Roy Chaudhury, adviser, department of health and family welfare, says the lack of regulation in clinical trials has seen India lose out to China, Malaysia and Singapore. "But this is set to change; we want India to once again be the centre for clinical trials."

To reduce bureaucratic tangles, the present 12 drug advisory committees will be replaced by one Technical Review Committee for speedy clearance of applications.

Source: *The Times of India, 19th September 2013*

Ranbaxy Unit to Come Under Certain Consent Degree Terms

Ranbaxy Laboratories, on Tuesday, said apart from the import alert on its Mohali facility, the U.S. health regulator had said that the unit would be subject to certain terms of the consent decree signed in January, 2012.

"The FDA also ordered that the Mohali facility be subject to certain terms of the consent decree of permanent injunction entered against Ranbaxy in January, 2012," according to United States Food and Drug Administration website.

The decree contains provisions to ensure CGMP (current good manufacturing practices) compliance at certain Ranbaxy facilities, including in Paonta Sahib and Dewas, India, as well as provisions addressing data integrity issues at those two facilities, the USFDA said. The USFDA had conducted inspections at the company's Mohali facility in 2012, resulting in certain observations. Ranbaxy shares on Tuesday closed at Rs.330 on the BSE, up 3.50 %.

Source: *The Hindu, 18th September 2013*

India's Drug Regulator Asleep on The Job?

Why does it take the US Food and Drug Administration (FDA) to detect quality lapses at Ranbaxy's plant at Mohali, Punjab? The US FDA has every right to inspect plants that supply drugs to its US citizens. Don't Indian health authorities have a similar responsibility to protect the health of Indians by ensuring that all plants that produce drugs for the Indian market consistently follow good manufacturing practices? If this is done, the likelihood of any plant that supplies drugs to an export market would be not found wanting. Globalisation calls for stricter standards at home, not just for production for export. It is time India's drug directorate got its act together.

A weak regulatory system has failed to ensure that drugmakers comply with quality norms. The state of apathy flows from a lackadaisical government machinery and drug administration overseen by truant babus. Their track record - be it in the procurement of TB drugs or medical equipment for faster diagnosis of the disease or ensuring that laboratories carry out rigorous quality checks on drugs - has been poor. These officials should be made accountable for failure to ensure timely availability of good quality drugs for both local consumption and exports. The need is to have tighter regulation.

Systems should also be in place for quality checks on generic drugs. India must move in the direction of the US where drugmakers comply with stringent norms on quality and crackdown on unethical marketing practices. Moreover, as Indian companies globalise, they will be exposed to multiple regulations and jurisdictions. The costs of regulatory mishaps due to compromising on the quality of drugs can be crippling. This is clearly avoidable, and it's the job of drug administrators to discover substandard drugs.

Source: *The Economic Times, 18th September 2013*

Children Given Hepatitis B Vaccine Orally Instead of Polio Drops

Four State health workers have been suspended in connection with the administering of Hepatitis B vaccine orally, instead of pulse polio immunisation drops, to 57 children at Khatul village in the Arambagh subdivision of the State's Hooghly district on Sunday.

The West Bengal Human Rights Commission took suo motu cognisance of the incident on Monday and sought a report from the State government.

Justice (retd) N.C. Seal and S.N. Roy, both members of the Commission, directed the Chief Medical Officer of Health, Hooghly, to file a report within three weeks.

"The children who had to be hospitalised have been discharged and the situation is totally under control," Manmeet Nanda, the District Magistrate, told The Hindu over the telephone.

B.R. Satpathy, director of State Health Services, said that 57 children were administered Hepatitis B vaccine that is not supposed to be taken orally.

"There is no harmful effect of the vaccine, but giving Hepatitis B vaccine instead of pulse polio immunisation drops is neither acceptable nor desirable," he said.

Stating that it was a case of clear negligence of duty on the part of the heath workers, he said that Chief Minister Mamata Banerjee has directed strong action against those responsible for the mix-up.

While 57 children were administered wrong vaccine, another 14 from adjoining areas who

were given the right vaccine were also hospitalised by their parents out of panic, Dr. Satpathy said, adding that all the children have been released.

"Though the children have been released from the hospital, we have decided to send medical teams door-to-door for the next two days for the satisfaction of the people," Mr. Nanda said.

There was a panic in the area when people got to know of the incident. Villagers held up senior district officials, including the Sub Divisional Officer (SDO), Arambagh, who rushed to the spot to pacify them on Sunday.

Over the past two years, no case of polio has been recorded in the country. The last case of polio was recorded in the State's Howrah district when in, January 2013 a two-and-a-half-year-old girl was found to be infected with wild polio virus.

Source: *The Hindu, 17th September 2013*

Strides Arcolab Too Gets USFDA Warning

Drug firm Strides Arcolab today said the US health regulator has issued a warning letter against a manufacturing facility of its subsidiary Agila Specialties.

"The sterile manufacturing facility 2 (SFF) at Bangalore of Agila Specialties Pvt Ltd, a wholly owned subsidiary of the company, has received a warning letter from the United States Food and Drug Administration (USFDA)," Strides Arcolab said in a filing to the BSE.

"The company is committed to work collaboratively and expeditiously with the USFDA to resolve concerns cited in the warning letter in the shortest possible time," it added.

USFDA had inspected SFF in the month of June 2013 and the inspection resulted in issuance of 'Form FDA 483' with observations. Strides had responded to the 483 observations by implementing corrective actions, it said.

Meanwhile, the company said the USFDA has cleared the oncology facility at Bangalore of Agila Specialties, which was also inspected recently by the US FDA.

"This facility has cleared the inspection with "Zero 483 status," Strides said.

Source: *The Economic Times, 17th September 2013*

Lupin Gets USFDA Nod For Insomnia Drug

Drug major Lupin today said it has received US health regulator's approval to market a generic version of Sanofi Aventis' Ambien CR Extended-release tablets, used in treating sleep disorders, in the American market.

The company has received final approval from the US Food and Drug Administration (USFDA) for its Zolpidem Tartrate Extended-release tablets in strengths of 6.25 mg and 12.5 mg, Lupin Ltd said in a statement.

Source: *The Economic Times, 17th September 2013*

'Gliptins' Carry No Risk of Pancreatitis, Says Study

Safety of anti-diabetic drugs has figured in many scientific discussions

With all the controversy surrounding the long-term side effects of anti-diabetic drugs, diabetologists have decided to put in extra effort to ensure that benefits overweigh the risks when they prescribe drugs.

One such recent study, conducted in Chennai, established that a much feared side-effect of a category of diabetes drugs did not manifest itself in patients.

In the August 2013 edition of the Journal of the Association of Physicians of India, a team from India Diabetes Research Foundation and Dr. A. Ramachandran's Diabetes Hospitals showed that long term use of a particular category of anti-diabetes drug, DPP-4 inhibitor, did not lead to a painful inflammation of the pancreas, as feared.

"There have been huge scientific and public discussions regarding the safety of anti-diabetic drugs lately. The major concern is that diabetes being a chronic lifetime disorder, the drugs prescribed should be taken for a long period. Therefore, long-term efficacy and any adverse effect of the drugs are a big concern, Dr. Ramachandran, one of the authors, says.

The DPP-4 inhibitor is advantageous as it causes very few episodes of hypoglycaemia (or low sugar). These drugs, which are slightly more expensive than other anti-diabetes drugs, are prescribed mostly for the elderly patients and in those with mild diabetes.

"These 'gliptins' have been in the market for some years, and there has been some concern regarding long exposure to the drugs leading to pancreatitis," he explains. These drugs come with the warning that they should not be prescribed to patients who are alcoholic or those with gall stones, as this would precipitate the risk of pancreatitis .

In the Indian population, there might be undiagnosed acute pancreatitis, often misdiagnosed as stomach pain, ulcer or gastritis. The fear is that if these patients are put on DPP-4 inhibitors, it might lead to pancreatitis with potentially fatal complications, says Dr. Ramachandran. "We do not prescribe these drugs to patients who are known alcoholics or who have gall stones, but we also decided to study how a batch of patients who have been on the drug for nearly five years now were faring with particular reference to the pancreatitis risk," he says.

In about 1,000 patients, the secretion of pancreatic enzymes, indicating the health of the pancreas, was monitored periodically for a year. "We even used a lower conservative cut-off for enzyme levels so that even borderline changes could be picked up. But we found that there was no enhanced risk for them."

The authors, Samith Shetty, Nanditha Arun, C.Snehalatha and Dr. Ramachandran, felt safe to conclude that the patients had a similar risk as in the diabetes control group (on non-gliptin drugs).

Source: *The Hindu, 12th September 2013*

BDR Pharma's Plea For CL on Cancer Drug Rejected

The Indian Patent Office has rejected Mumbai-based BDR Pharmaceutical's application for compulsory licence on cancer drug Dasatinib, according to an affidavit filed by Bristol Myers Squibb, the patent holder for the drug.

Compulsory licensing is a provision provided by international intellectual property protection agreements under which governments can allow companies to produce generic versions of patent-protected drugs under certain conditions, including if they are found to be out of reach of the public.

Dasatinib, which Bristol-Myers Squibb sells as Sprycel, is used in the treatment of chronic myeloid leukaemia. In India, a month's dose of this drug costs about Rs 1 lakh. BDR Pharmaceutical had applied for a compulsory licence (CL) on this drug in March and said its version will cost Rs 8,100/month.

In its affidavit filed in the Delhi High Court last month, the US-based drugmaker has accused BDR Pharmaceutical of suppressing information regarding the status of its patent.

"It is respectfully submitted that, as per the knowledge of the plaintiffs, the Controller of Patents has not found a prima facie case as regards the defendant's application under Section 84 of the Patents Act, 1970 and the same stands rejected," Bristol Myers has said in its affidavit, a copy of which was reviewed by ET.

"It is further submitted that the defendants are guilty of suppression as they have not informed this hon'ble court about the aforementioned order of Controller of Patents, nor have they supplied a copy of the application to the court," the affidavit added.

However, BDR Pharmaceutical's managing director, Dharmesh Shah, denied that the company's compulsory licence application has been rejected.

Gopakumar Associates, counsel for BDR Pharmaceutical, said it has not received any rejection notice from the Patent Office in this regard. Bristol Myers Squibb did not respond to ET's emailed query regarding the Indian company's denial of CL rejection.

Patented drugs have marketing exclusivity for 20 years. Bristol-Myers Squibb's patent for dasatinib expires in 2019. It is also one of the drugs the health ministry has proposed for CL under Section 92 of the patent Act.

Over the last one year, the Indian government has used CL to push down prices of some essential drugs and make them more affordable for the public. This pro-patient stand has raised tensions with multinational drug makers.

The health and commerce ministries are considering a proposal to put three cancer drugs, including dasatinib, under compulsory licence.

Source: *The Economic Times, 12th September 2013*

It's A PATH of Violations, All The Way to Vaccine Trials: House Panel

Committee questions roles of ICMR, Drug Controller in the "intriguing" 2010 episode

Accusing the international organisation PATH (Programme for Appropriate Technology in Health) of exploiting with impunity the loopholes in the system during a trial of Human Papillomavirus (HPV) vaccines, a parliamentary panel has also questioned the roles of the Indian Council of Medical Research and the Drug Controller-General of India in the entire episode.

The issue pertains to trials conducted by two U.S.-based pharmaceutical companies through

PATH on tribal school girls in Khammam district in Andhra Pradesh and Vadodara in Gujarat in 2010. The trials were stopped only after the matter received media attention following the death of seven girls.

In its report on "Alleged Irregularities in the Conduct of Studies using HPV Vaccines by PATH in India" presented to Parliament, the committee has said ICMR representatives apparently acted at the behest of PATH in promoting the interests of the vaccine manufacturers, and recommended that the Health Ministry review the activities of the functionaries of the Council involved in the PATH project

As for the DCGI, the approvals of clinical trials, marketing approval and import licences by the agency "appear to be irregular" and its role "in this entire matter should also be inquired into."

The Department of Health Research/ICMR "have completely failed to perform their mandated role and responsibility as the apex body for medical research in the country. Rather, in their over-enthusiasm to act as a willing facilitator of the machinations of PATH, they have even transgressed into the domain of other agencies which deserves the strongest condemnation and strictest action against them."

The committee failed to understand why the ICMR "took so much interest and initiative in this project when the safety, efficacy and introduction of vaccines in India are handled by the National Technical Advisory Group on Immunisation."

How could the ICMR commit itself to supporting "the use of the HPV vaccine" in an MoU signed in 2007, even before it was approved for use in the country, which actually happened in 2008? The committee also questioned the ICMR's decision to commit itself to promoting the drug for inclusion in the Universal Immunisation Programme before any independent study on its utility and rationale of inclusion in the UIP was undertaken.

Describing the entire matter as "very intriguing and fishy," the committee said the choice of countries and population groups (India, Vietnam, Uganda and Peru); the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunisation programmes of the respective countries "are all pointers to a well-planned scheme to commercially exploit a situation."

Had PATH been successful in getting the HPV vaccine included in the universal immunisation programme of the countries concerned, windfall profits would have been generated for the manufacturer(s) by way of automatic sale, the committee said. It asked the government to take up the matter with these countries through diplomatic channels.

Flouting ethics

Drawing attention to gross violation of ethics during the conduct of trials, the committee members said that in Andhra Pradesh out of 9,543 consent forms, 1,948 had thumb impressions, while hostel wardens signed 2,763 others. In Gujarat, out of 6,217 forms, 3,944 had thumb impressions. The data revealed that a very large number of parents/guardians were illiterate and could not even write in their local language, Telugu or Gujarati.

It was shocking to find from one of the reports that out of 100 consent forms for Andhra Pradesh, project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact, the legality of the State government directing headmasters of all private/government/ashram/schools to sign the consent forms on behalf of parents/guardians was highly questionable. The absence of

photographs of parents/guardians/wardens on consent forms and of signatures of investigators, the fact that signatures of parents/guardians did not match with their names; and the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms spoke of grave irregularities, the report said.

The committee said PATH should be made accountable and the government should take appropriate steps in the matter, including legal action against it for breach of laws of the land and possible violations of laws of the country of its origin.

Describing this act of the PATH as a clear-cut violation of human rights and case of child abuse, the Committee has recommended that the National Human Rights Commission and the National Commission for Protection of Children Rights take up this matter. The National Commission for Women should also take suo motu cognisance of this case as all the poor and hapless subjects were female.

The Health Ministry should report the violations indulged in by PATH to the World Health Organisation and the United Nations Children's Fund so as to ensure that appropriate remedial action was initiated worldwide, the committee said.

Source: *The Hindu, 2nd September 2013*

CHENNAI BASED PHARMA COMPANY FOR SALE

A running pharmaceutical manufacturing and marketing company having facilities to manufacture oral liquid and suspension, Tablet and Powder with 30 years experience operating in Tamilnadu and Kerala States, situated in Chennai Suburbs with its own manufacturing unit with ethical marketing set up wants to sell their company

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