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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2010

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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ISSUE : 8 Oct. - Nov. - Dec. 2010

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CONTENTS **Page No.**

EDITORIAL

Dear Readers,

This is the 8th Issue of our quarterly newsletter since inception. In the last issue we partially covered some programs of IPA Convention held at Chennai. In this present issue we have covered other lecture programs held during this convention, as many of our pharmaceutical manufacturers desired to enrich their knowledge on CRO base. Many manufacturers who are exporting their products shall have their knowledge of bioequivalent study. The BA/BE studies are necessary to assess pharmaceutical products for its absorption and excretion namely pharmacodyanamic / pharmacokinetic study. So this article give full information about the BA/BE studies through a CRO, further our Country situated in Zone – IV climatic condition, it is necessary to store the pharmaceutical products in proper storage condition as well as during transits, hence this article is important for our readers to practice the storage conditions.

The Govt. of India (Ministry of Health) issued the notification regarding "Registration of cosmetic products to be imported into the country". I request all our readers to go through the notification and appraise the cosmetics manufacturers as well as importers to get the registration certificates before April 2011.

The Antioxidants food supplements, safety considerations and facts about Antioxidant therapy and also about the Antibiotics and its classification is given as information.

Some parliament questions and answers from Rajya Sabha and Lok Sabha held during the month of August 2010 are added as new subject.

We have covered many important news items including various Pharmacy college functions as well as our professional news items.

I thank Mr. Prafulla Chandra, Associate Editor and Mrs. Pratima Mathur, Executive Editor for their co-operation to bring this issue successful.

I also thank all the members of the Editorial board and the Advisory board for helping me to publish this issue in a time bound manner. I hope the readers will be benefited from this bulletin.

We request our readers to offer their valuable suggestions and comments about Pharma Web, which will enable us to improve future issues

With best regards

Mr. R. Narayanaswamy

ARTICLES

DEVELOPING INDIA AS A GLOBAL CRO BASE

Mr. T. S. Jaishankar
Quest Life Sciences (P) Ltd.
Chairman- Confederation of Indian Pharmaceutical Industry(CIPI)
Advisory Board Member-Journal for Clinical Studies-UK

DEVELOPING INDIA AS A GLOBAL CRO BASE

India is one of the fastest growing clinical research destinations with a growth rate that is two and a half times the overall market growth.

QUEST LIFE SCIENCES (P) LTD.,

- The Clinical trials(Phase I-IV) segment is valued at USD 42b and constitutes 65% of global clinical research spending.
- There has been steady globalization of clinical trials in the last decade with the share of emerging markets becoming increasingly dominant.

QUEST LIFE SCIENCES (P) LTD.,

- India is ranked third among emerging markets and is growing the fastest in its number of industry-sponsored Phase II-III sites.
- India is rated as one of the most attractive destinations for clinical trials by various surveys.
- India is emerging as a "sweet spot", as compared to most emerging markets, with a robust 31% p.a. growth over the last four years.

QUEST LIFE SCIENCES (P) LTD.,

- India now participates in over 7% of all global Phase III and 3.2% of all global Phase II trials.
- India has a high disease burden with a growing share of non-communicable diseases.

QUEST LIFE SCIENCES (P) LTD.,

- As a result of the diverse patient mix, India has one of the fastest subject recruitment rates globally.
- India's medical infrastructure both public and private is speedily gearing up to provide the necessary enabling environment for smooth clinical trial conduct.
- The Indian healthcare infrastructure has a lot to offer as the potential site landscape is as diverse as its patient population.

QUEST LIFE SCIENCES (P) LTD.,

- GCP compliant sites in India offer high site efficiency and data quality.
- Human resource capacity and capability is ramping up fast to effectively service the growing opportunity.

QUEST LIFE SCIENCES (P) LTD.,

There are twenty CAP certified central laboratories including international players providing esoteric services.

Centrals labs offer a strong value proposition with comprehensive test menu and a quality driven approach.

Government is providing significant impetus to training and capability building of investigators and clinical research professionals.

Ethics Committees are being strengthened with increased focus on training and oversight.

Site management organizations (SMOs) are playing an increasing role in clinical operations.

India's regulatory environment has undergone significant evolution in the last few years.

A number of initiatives to further strengthen the regulatory environment are being planned and implemented.

Regulatory approval timelines are getting streamlined and further reduced.

India is poised to become one of the top 10 pharmaceutical markets by 2015 with CAGR of 12%

The commercial attractiveness of India as a "clinical trial destination"

India offers significant cost arbitrage for conduct of clinical trials.

Supported by an enabling logistics, IT and cost efficiencies.

System Capabilities

- India has consistently been ahead of other countries as a destination for outsourcing IT/ITES work.
- Growth in India's IT/ITES export is driven by its ability to develop a successful global delivery model and robust IT/Telecom infrastructure
- Domain expertise
- Cost advantage

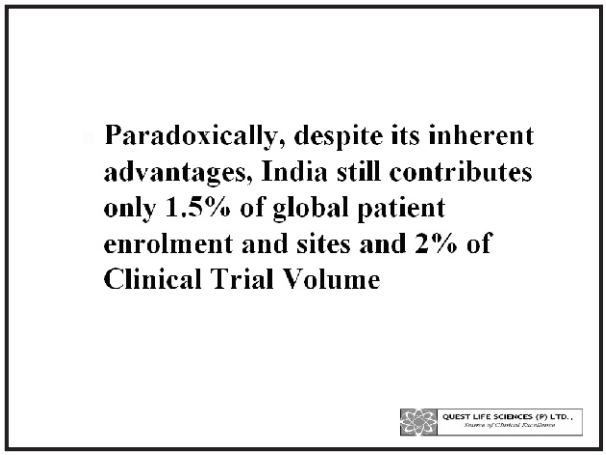
- Abundant, skilled and English speaking workforce has provided adequate platform for the companies to scale up operations.
- India offers significant cost advantage to service providers and sponsors
- India's advantage is also evident from the significant growth witnessed by the segment in the last three years.

- CDM, BS, PV and MW constitutes major clinical trial allied services.
- Total spend on these services is estimated at USD 22b and accounts for 35% of total global clinical research spend.
- Changes in landscape of clinical trial has made companies realign their allied services strategy through outsourcing and offshoring.

COMMERCIAL ATTRACTIVENESS OF INDIA AS A "PHARMACEUTICAL MARKET".

- Most global CROs have established a direct and indirect presence in the Country, while Indian CROs are steadily globalizing their reach and expanding their scale.
- Most CROs have presence across the entire services spectrum.
- Indian CROs are extending their business development and delivery footprint across frontiers.

- Global sponsors have set up captive operations while a number of CROs focused on clinical research have mushroomed.
- Clinical trial activity is conducted in India through a mix of business models- captive, outsourcing and partnerships.
- Big Pharma today carry out more than 60% of clinical trials in India through their captive centres.



TRAINING / PLACEMENT FOR PHARMACY PROFESSIONALS

Tamilnadu Pharmaceutical Sciences Welfare Trust is creating a database for the placement of graduates and post-graduates in Pharmacy who require job opportunities in Pharmacy field like academics / industries (production, QA & QC) / marketing / research and regulatory affairs, etc. The application format is available at our website www.pictrust.com. Persons who are fresh graduates or experienced in pharmacy field may fill the same and send it to us online.

DEVELOPING GOOD STORAGE PRACTICES

Mr. R. Srinivasan
National Executive Committee Member (South Zone), All India Organization of Chemists and Druggists
At the pre-conventional workshop for Community and Hospital Pharmacists on HIV/AIDA
Organised by IPA and Commonwealth Pharmacists Association (CPA)

Developing Good Storage

- Medicines are temperature sensitive - require controlled temperature conditions. To be handled with special care throughout the Distribution Chain until it reaches the end consumer.
- Indian Pharmacopoeia prescribes specific storage conditions for every drug formulation – potency of the medicines depends on storage at every stage.

How important is storage

- Medicines may die well before their Date of Expiry if not stored properly.
- Its potency, stability, efficacy and shelf life have direct relevance to storage.
- Schedule P of D&C Rules deals with potency period of drugs in direct relation to storage conditions specified in Indian Pharmacopeia - thus storage conditions are mandatory.

Storage conditions defined

- Recommendatory
- Manufacturers, based on their own stability tests and as per IP and D&C Rules recommend specific storage requirements on the packs of the medicines
- Definitions of Storage
- Schedule P of Drugs & Cosmetics Rules lists Life period of Drugs and Conditions of storage ⊕
- In a Cool Place.
- In a well closed container protected from light
- In cold place
- In cool place protected from light
- Schedule P of D&C Rules
- At temperature not exceeding 20°C
- Between 2 ° C & 5 °C
- Temperature not exceeding 25 °C
- Temperature between 4 °C & 6 °C
- Minus 20 °C

Storage conditions on packages

- Keep in a cool, dry place.
- In a dark, cool place,
- protect from heat and light
- store between 30 °C, protected from moisture
- store below 25 °C
- store in a dry place between 2 °C & 8 °C

Definitions .....

Store at a temperature bet. 2 °C & 10 °C
Store at +2 °C to 25 °C
Store below 20 °C
Store away from sunlight
Store below 30 °C
Do not freeze
Store at controlled temp.bet. 15°&30 °C
Store at room temperature

- **Storage - the problem**
  - The importance of storage are not conveyed with clarity in labels due to
  - Confusing terminology
  - No hormonization in the language used
  - do not convey the correct storage in a language that can be easily understood by Stockists, Retailers & Consumers
  - Lack of awareness by stakeholders
- **Storage - the practical solution**
  STORE products requiring minus 10°&14 °C in a FREEZER.
- STORE products - Insulin, Vaccines, etc requiring min.2 °C and maximum 10 °C- Not to be frozen- WITH A CALIBRATED COOLING GADGET
- STORE products requiring less than 30 °C in an air-conditioned room
- STORE ALL other products protected from dust, direct exposure to heat, sunlight and moisture in a clean storage area

Legal protection ?

- IMPORTANCE OF Storage from yet another VERY critical point.. ?
- In the event of a product found in your possession to be
  - sub-standard
  - mis-branded
  - adulterated or
  - Spurious

  What is your protection?

Protection for a dealer under D&C Rules

- **Section 19 of Rules state:**
- → a (dealer) person, not being a manufacturer of a drug SHALL NOT BE LIABLE for Contravention of Section 18 of the D&C Rules, if he proves
- → A) that he acquired the drug from a duly licensed manufacturer, distributor, or dealer thereof;
- → B) that he did not know and could not, with reasonable diligence, have ascertained that the drug in any way contravened the provisions of that section and
- → C) that the drug while in his possession was **properly stored** and remained in the same state as when he acquired it.

Present scenario

- Multiple layers of supply chain channels
- Lack of awareness
- Transit; under unfavorable climate conditions exposed to sunlight, high temperature
- Storage of products requiring storage at <25°c, by wholesalers in ambience storage area
- Storage at Retail counters exposed to sun light

Present scenario contd ..

- Storage at Retail counters at >30 to 40°c
- Improper storage inside the refrigerators
- Absence of generator back up
- Huge volume in terms of SKUs
- Mind set - Mental block

Positive side

- With the entry of few Retail Chains and emerging life style malls, Retail Chemists have started air-conditioning the Pharmacies, protected from heat & dust;
- Pharmacy ambience becoming more professional
- Competition-Acceptance - to adopt professional practices

What is Cold Chain ?

- Significant number of new products in the pipe line of Global Pharma Industry fall under Biologics category.
- Increasing number of Cold chain products in Indian Pharma market
- Handled and stored at various stages- Air/sea customs, transporters, distributors, Retailers, doctors & hospitals
- Storage & handling by stakeholders required to be monitored in the entire supply chain to ensure patients get the products without compromise in quality .

Guidelines on Cold Chain Management

What are Cold Chain Medicines?

Cold chain medicines are those that require special temperature controlled cold storage to maintain their quality and efficacy.

There are two commonly recommended temperatures specified on the labels of cold chain products:

1. Products requiring temperatures of between 2°C and 8°C
2. Products requiring temperatures of around (-10°C) and (-20°C)

What is Cold Chain Management?

A cold chain is an uninterrupted series of storage and distribution activities that maintains products at a required temperature range of 2°C and 8°C or between 10°C and -20°C as per their requirements.

Why is Cold Chain Management Important?

Cold chain management in pharmaceuticals is important to ensure that the right quality is maintained during storage and transportation, and also to meet the regulatory commitments. Regulatory guidelines and standards around the world focus on the right storage and transportation, and adhering to these standards is important.

Cold chain products are sensitive biological substances that can become less effective or lose their potency if not stored properly. For example, products that are required to be stored between 2°C to 8°C could become ineffective if:

i. They are frozen or stored below 2°C
ii. Exposed to temperatures above 8°C
iii. Exposed to direct sunlight or fluorescent light

The loss of potency is cumulative and irreversible.

In short, when products are exposed to conditions outside the established temperature range, their quality may be negatively affected, reducing their assigned shelf life, diminishing their effectiveness or making them ineffective.

Though the exposed product may look the same it will not have the required potency, and have a direct impact on patient safety.

So it is important that the right temperature is maintained throughout the distribution chain, starting from the dispatch of the product from the manufacturing site to when it reaches the patient.

Guidelines for Distributors for Handling Cold Chain Pharmaceutical Products

- **Standard Operating Procedures:**

Distributors/ wholesalers are important stakeholders in pharmaceutical distribution. They play a vital role in proper cold chain management as products spend a considerable time in their custody.

It's quite common for wholesalers to handle multiple products of different companies, which makes storage and handling complex. Hence, it is important to have comprehensive documented standard operating procedures so that each product is stored and handled at the right temperature as prescribed by the manufacturers.

- **Training:**

There should be a training programme for personnel on standard operating procedures for handling pharmaceutical consignments. Employees handling packing and dispatch should be specifically trained in packing procedures.

- **Receipt of Products:**

The pack containing the products should be physically inspected. It should not be dirty, damaged or torn and safety seals or tapes should be intact and not tampered with.

After unpacking, the product should be immediately transferred to the storage facility. Instructions on the product packages, labels and invoice should be followed.

The supplier should be notified immediately if any temperature deviation is noticed.

Storage:

- Stockists / distributors should have adequate cold storage infrastructure - cold rooms or special refrigerators to store pharmaceutical products at 2°C to 8°C. Products requiring sub-zero temperatures should be stored in a deep freezer.

- The exclusive areas where the cold chain products are stored should be clean.
- Products should be stored in an orderly manner in the racks.
- Medicines should be stored according to company/ product/ batch.
- Products that are expiring first should be placed in the front.
- The practice of FEFO (First Expiry First Out) should be followed.

- Medicines should be stored within the specified storage area only. In no case should cold chain products be stored outside the refrigerator/ walk-in cooler.
- Entry to the storage room should be restricted to authorized personnel.
- Always plan for sufficient storage space in the refrigerator to accommodate stocks purchased.
- Orders should be placed once a week to stagger purchases and manage storage capacity.

What a domestic refrigerator used to store medicines should be like

i) The refrigerator should be used exclusively to store medicines.

ii) It should maintain a temperature of between 2°C and 8°C without major fluctuations. The freezer compartment should maintain a temperature of below -15°C. If the refrigerator is not frost-free, ice should not be allowed to build up more than a quarter inch.

iii) It's better to use special refrigerators like Visicoolers and Ice Lined Refrigerators that are now available without freezers. These are capable of maintaining uniform temperatures of 2°C to 8°C much better than domestic refrigerators. Among domestic refrigerators, frost-free models are recommended. These refrigerators do not have heating cycles, but remain frost-free with low levels of frequent warming temperatures.

iv) The refrigerator should be well-maintained

v) The seals should be in good condition and there should be no water or coolant leaks.

vi) The door should close properly and automatically

vii) Food, beverages and other drugs should not be stored along with medicines in the same refrigerator. This interferes with temperature control and may contaminate the medicines.

How to store medicines in a domestic refrigerator in an appropriate way

a) Placement of the refrigerator – The refrigerator must be placed away from direct sunlight and any other source of heat -- for example, a warm external wall. Doors must not be opened unnecessarily.

b) The power source – Accidental disconnection from the power source can cause damage to the medicines, particularly if it is unnoticed for a long period. Ideally, the power source must be isolated and kept under lock and key.

c) Place water bottles or ice packs/ gel packs inside the refrigerator – This will help stabilize the temperature in the refrigerator compartment as cold air is distributed from the freezer in most frost-free refrigerators.

d) Place water-filled plastic containers in the lower shelves and door – This reduces warming periods when the refrigerator is opened. This is particularly useful if the refrigerator breaks down because of a power shutdown or any other cause.

e) Stabilize the temperature of the refrigerator before stocking – This will minimize the effect of temperature variations on medicines.

f) Keep medicines in plastic containers – This allows easy identification of medicines, thus minimizing the time the door is kept open. Avoid glass and metal containers since they offer less buffering against temperature deviations. Air circulation between enclosed plastic containers can be maintained by not packing them tightly.

g) Door of the refrigerator – Medicines should not be stored in the door of the refrigerator. The door lining should be checked regularly for any leakage, and worn-out linings replaced immediately.

h) Chiller of the refrigerator – Medicines should never be stored in the chiller.

i) Monitoring the temperature inside the refrigerator – Each refrigerator should have a good quality temperature monitoring device. The device should be placed in a central location and the temperature recorded regularly every day.

Power Backups:

- There should be a dedicated power backup to ensure uninterrupted power supply to the cold rooms and an uninterrupted cold chain.
- The power backups should be routinely tested at night or on holidays to test their effectiveness.
- Instead of a generator, the refrigerator should be connected to an inverter so that power is automatically restored.

Qualification of Cold Rooms/ Refrigerators:

- There should be an annual mapping/qualification of cold rooms / refrigerators to ensure uniform temperatures in all parts of the cold room / refrigerator.
- The qualification should be done by professional agencies with multiple temperature monitors, covering all parts of the room.

- The temperature mapping should be done under the following conditions:

1. In an empty cold room / refrigerator.
2. With a full load.
3. At different times of the year, preferably once in summer and once in winter.

- Qualification should identify the hottest and coldest points in each cold room / refrigerator.

- **Always remember that for medicines requiring temperatures of between 2°C and 8°C, any exposure to below 2°C is far more dangerous than exposure above 8°C.** Products exposed to sub-zero temperatures may completely lose their potency, rendering them useless. Adequate precautions should be taken to set the thermostatic controls in the cold room / refrigerator to prevent such excursions.
- The qualification report should be documented and made available for reference later.

Temperature Monitoring:

- Proper temperature monitoring is key to cold chain management. A temperature monitoring device should be placed in the coldest point in the storage unit, adjacent to the medicines. The temperature must be read and documented at least twice each day, once when the premises opens and once at the end of the day. Immediate action must be initiated to correct storage temperatures that are outside the recommended ranges. All staff members working with medicines should be familiar with proper temperature monitoring. Mishandled medicines should not be administered.

- Cold rooms / refrigerators should have a data logger to record temperatures on a continuous basis 24 x 7.
- An alarm or hooter should go off if the temperature goes outside the prescribed limits in the cold room/ refrigerators.
- Temperature data loggers should be calibrated annually to ensure accurate recording.
- Temperature data loggers should have sufficient battery and shelf life.

- Dataloggers should be replaced once every three years.

A round-the-clock monitoring system might be considered to alert staff to emergencies after working hours, particularly if large medicine inventories are maintained.

Packing for Despatch:

- Packing must be done as per the
- prescribed system or as recommended by manufacturers by trained persons
- Coolants (ice packs) must be conditioned in the deep freezer (temperature between -20oC to -15 oC) for a minimum of 48 hours to five days before use to ensure the desired effect throughout the transit period.

- The duration of this pre-conditioning will vary depending on the ice packs used.

The optimal time to condition the ice packs should be established during the qualification time of the packing system.

- The number of ice packs and their arrangement in the thermocol box should be as per the prescribed system.

- There should be no direct contact of the ice packs with the product, as this may damage the labels or packages and cause the product to freeze, adversely affecting its quality and potency.
- The time taken to pack the product in the assigned area, during which the product remains outside refrigerated conditions, must be kept to a minimum.

- The temperature of the packing room must be monitored and recorded during packing. The packaging area should be air-conditioned to minimize temperature excursions.
- A datalogger must be placed near the product without touching the ice packs to determine the temperature of the product during transit.

- Packing components must be qualified to ensure that they maintain the right temperature taking into account:

o The means of transportation employed for distribution.
o The destination of the products to be delivered.
o The route to be used.
o The time taken to reach the destination.

Preventive Maintenance:

- There should be a documented preventive maintenance programme for all major equipment so that they are always in good running condition.
- There should be an annual maintenance contract with the supplier / service provider for important equipment like cold room, refrigerators, freezers, gensets, inverters, airconditioning units etc.

Contingency Plan:

- There should be tie-ups with regional service centres they can be contacted and can reach at short notice to repair major problems.
- All efforts should be made to minimize temperature excursions and transfer or restore the products to the prescribed storage limits.

Excursion Handling:

- This is a very important part of cold chain management. Any temperature excursion during storage and distribution should be recorded and immediately reported to a quality assurance (QA) representative or a person responsible for the cold chain. The manufacturer concerned should also be notified of such excursions.

- The QA representative should assess the potential effect on the safety, efficacy and quality of the product. Till that time, the suspect medicines should be isolated in a refrigerator or cold room in a container labeled **"Quarantined"**. They should not be used until advised.

Guidelines for Retailers / Chemists for Handling Cold Chain Pharmaceutical Products

- **SOP for handling cold chain products**
- **Purchase-**
- **storage-**
- **sales-**
- **returns**

Purchase of Cold Chain Medicines:

- Cold chain medicines should be purchased only from the authorized stockist of the manufacturer or marketing company. **No purchases should be made from unauthorised sources as you can never be sure about the quality and genuineness of the medicine.** Besides, you can never be sure if the products were stored properly.
- Retailers should ensure that the stockist/ wholesaler supplying the medicines maintains the cold chain properly during storage and transit. If not, he should report to the manufacturers and switch to another stockist who follows the correct practices.

Receipt of Products:

- Physically inspect the temperature and expiry date of the pack. Ensure that it is within the stipulated range. The pack should be intact with seals and tapes and not tampered with.
- Never accept stocks from the stockist if they don't have proper temperature-controlled packing or you have reason to suspect that the temperature has not been maintained properly in transit.

- If you or your personnel personally visit the stockist to buy the medicines, take a full shipper in the recommended cold chain packing from the stockist. If you are buying loose or less than shipper quantity, ensure that you carry along special packs or containers that can maintain the proper temperature during transit.
- Immediately transfer the stock into the refrigerator/ deep freezer as per the storage condition prescribed on the product pack.

Storage:

- Retailers should have the necessary infrastructure to store cold chain products -- adequate size Ice Lined refrigerators/ double-door domestic refrigerators for storing products between 2°C and 8°C and deep freezers for storing products at sub-zero temperatures.
- Products requiring temperatures of between 2°C and 8°C should be stored in specially designed refrigerators like Visicoolers.

- All temperature-sensitive medicines/ vaccines should be stored in a central place in the refrigerator or freezer as per product storage requirements. They should not be stored in the door, chiller or at the bottom of the storage unit, and be sufficiently away from the walls to allow the air to circulate.
- There should be air-conditioning in the shop, with temperatures of between 15°C and 25°C to store normal medicines and also to provide the right ambient temperature to operate refrigerators and freezers.

- **Eatables or beverages should not be kept in the fridge or freezer used to store medicines.**
- Glass bottles filled with water should be placed in the door and the bottom shelf to ensure uniform temperature in the refrigerator.
- Purchases should be staggered to ensure proper storage. Do not overstock cooling units.
- Products requiring temperatures of between 2°C and 8°C should never be frozen.

- Stocks in the cooling units should be regularly rotated.
- All medicines should be stored batch-wise on a `First In First Out/ First Expiry First Out' basis.
- The temperature of the cooling units must be checked and recorded at least twice a day. Technical assistance must be summoned in the event of any abnormal fluctuation of temperature.
- Ideally, there should be a well-trained person in charge of operating the cooling units.

- **Never shut off the electricity at night or on holidays as it can severely hamper the cold chain and the quality of the medicines.**

Power Backup:

- Since power cuts are common it is absolutely essential to install inverters/ auto start generators of the right capacity to ensure uninterrupted power supply and maintain an effective cold chain.

- It is important that the power backup is automatically activated at night or on holidays when the shop is closed to ensure that the refrigerators or freezers are functional.

Continuous Temperature Monitoring:

- Refrigerators/ freezers should have a datalogger to record temperatures on a continuous basis 24 x 7. If a datalogger hasn't been installed, there should at least be a min-max thermometer.

- The datalogger/ thermometer should be kept in the centre of the refrigerator.
- Trained personnel should review the temperature data on a regular basis to see if the correct storage temperature is maintained and take corrective action where required.
- Temperature dataloggers/ thermometers should be calibrated annually to ensure accurate temperature recording.
- Temperature dataloggers should have sufficient battery and shelf life.

- They should be replaced every three years.

Preventive Maintenance:

- There should be a documented preventive maintenance programme for all major equipment so that they are always in good running condition.
- There should be an annual maintenance contract with the supplier / service provider for important equipment like refrigerators, freezers, gensets, inverters, air-conditioning units etc.

Contingency Plan:

- There should be a documented procedure to train personnel to handle contingencies like refrigerator/ freezer/ power backup breakdown or any other event that could compromise cold chain and product safety.
- The list of contact numbers of necessary people should be readily available so that they can be immediately contacted.
- There should be tie-ups with regional service centres so that they can be contacted and can reach at short notice for repairs of major problems.

Educating Patients / Customers:

- When patients come to retailers to buy cold chain medicines, the buyers should be informed about proper storage and handling.
- Retailers should provide some protective packaging to maintain the cold chain till the medicine reaches the patient. **If possible, retailers should deliver the cold chain medicines to the patient's home.**
- Patients should be informed that cold chain medicines requiring temperatures of between 2°C to 8°C **should never be frozen.**

- **Cold chain products, once sold, should never be taken back by the retailer as there's no way of telling how the medicines were stored by the patient. Patients should be informed about this while they are being sold the medicines.**

For the kind attention of Pharmaceutical manufacturers / Pharma educational institution

TRAINING / PLACEMENT VACANCIES FOR PHARMACY GRADUATES

TNPSWT is creating a database for placement of graduates / post-graduates in Pharmacy who require job opportunities like academics / industries (Production, QA & QC) / marketing / Research and Regulatory Affairs, etc.

You are requested to forward the details of positions available in your organisation to enable us to communicate to the appropriate candidates. The details may be emailed to us at pictrust@hotmail.com

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of health)

NOTIFICATION

New Delhi, the 9th April, 2010

G.S.R. 426(E)/- Where as a draft of certain 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), (23 of 1940), at pages 6 to 11 of the Gazette of India Extraordinary, Part II, Section,3 Sub-Section (i) dated the 2nd February 2007, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 63(E) dated the 2nd February 2007 inviting objections and suggestions from all Persons likely to be affected thereby, before the expiry of a period of forty-five day from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And, whereas copies of the said official Gazette were made available to the public on the 6.2.2007;

And, whereas, objections and suggestions received from the public on 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 said Act, 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 (4th Amendment) Rules, 2010.

(2) They shall come into force with effect from 1st day of April 2011.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), in Part XIII, for the heading "IMPORT OF COSMETICS" shall be substituted.

3. In the said rules, for rule 129, the following rules shall be substituted, namely:-

"129. Registration of cosmetic products imported into the country.-No cosmetic shall be imported in to India unless the product is registered under the rules by the licensing authority appointed by the Central Government under rule 21 or by any person to whom such powers may be delegated under rule 22.

129A. Form and manner of application for Registration Certificate.

(1) An application for issue of a Registration Certificate for cosmetics intended to be imported into India shall be made in Form 42 either by the manufacturer himself or by his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer and shall be accompanied by a fee of two hundred and fifty US dollars or its equivalent to Indian rupees for each brand of cosmetic. The application shall be accompanied by a treasury challan as specified in sub-rule (3) along with the information and undertaking as specified in Schedule D (III) duly signed by or on behalf of the manufacturer or by his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer.

(2) An authorisation by the manufacturer to his agent in India shall be duly authenticated either in India before a First Class Magistrate or in the country of origin before such an equivalent authority.

(3) The fees shall be paid through a challan in the designated branches of Bank of Baroda either in US dollars or in equivalent Indian rupees under Head of Account "0210 - MEDICAL AND PUBLIC HEALTH, 04 PUBLIC HEALTH, 104-FESS AND FINES" and the original copy of the treasury challan shall be submitted alongwith the application for product registration.

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-MEDICAL AND PUBLIC HEALTH, 04 PUBLIC HEALTH, 104-FESS AND FINES" and the original receipt of the said transfer shall be treated as an equivalent to the bank challan subject to the approval by the Bank of Baroda that they have received the payment.

(4) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government, as may be, required for examination, tests and analysis of cosmetics.

(5) A fee of one hundred US dollars or its equivalent shall be paid for a duplicate copy of the registration Certificate, if the original is defaced, damaged or lost.

129 B. Registration Certificate for the import of cosmetics manufactured by one manufacturer.- A single application may be made and a single Registration Certificate in Form 43 may be issued in respect of import of one or more than one cosmetics manufactured by the same manufacturer:

Provided that the cosmetics are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit.

129 C. Grant of Registration Certificate.- (1) On receipt of an application for Registration Certificate in the form and manner specified in rule 129A, the licensing authority shall, if satisfied, issue a Registration Certificate in form 43 subject to the conditions of the registration certificates in form 43:

Provided that if the application is complete in all respects and information specified in Schedule D III is in order, the licensing authority shall, within six month from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months, as the licensing authority may deem fit.

(2) If the applicant does not receive the Registration Certificate within the period as specified above, he may appeal to the central Government and the Central Govenment may after such enquiry into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.

129D. Duration of Registration Certificate.- A Registration Certificate, unless it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:

Provided that if application for a fresh Registration Certificate is made within six months before the expiry of the said certificate, the existing Registration Certificate shall be deemed to continue to remain in force until orders are passed on the application.

129E. Suspension and cancellation of Registration Certificate.- If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefor, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly of in respect of some of the cosmetics to which it relates.

Provided that a person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the said appellant an opportunity of being heard pass orders as it thinks fit.

129F. Prohibition of import of certain cosmetic.- No cosmetic, the manufacture, sale of distribution of which is prohibited in the county of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.

129G. Standard for imported cosmetics. No cosmetic shall be imported unless it complies with the specifications prescribed under Schedule S and Schedule Q or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case the cosmetic is not included under Schedule S, it shall meet with specifications under the rules and standards applicable to it in the country of origin.

129H. Labeling and Packing of Cosmetics.- No cosmetic shall be imported unless it is packed and labeled in conformity with the rules in Parts XV. Further the label of imported cosmetics shall bear registration certificate number of the product and the name and address of the registration certificate holder for marketing the said product in India".

4. In SCHEDULE A to the said rules, after Form 41, the following Forms shall be inserted namely:-

"Form 42
(See rule 129 A)

Application for issue of Registration Certificate for import of cosmetics into India under the Drugs and Cosmetics Rules, 1945.

I/We*.....
(Name and full address) hereby apply for the grant of Registration Certificate to the manufacturer, M/s ..... (full address with telephone, fax and e-mail address of the foreign manufacturer) for his manufactred cosmetics meant for import into India.

1. Name of cosmetics along with their brand name and pack size(s) and variants for registration.

(1)	(4) .....
(2)	(5) .....
(3)	(6) .....

2. I/We* enclose herewith the information and undertaking specified in Schedule D (III) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below:-

3. A fee of ..... for registration of cosmetics for import as specified at serial number 2 above has been credited to the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and cosmetics Rules, 1945 - Central" vide Challan No. ..... dated ..... (attached in original).

4. Particulars of premises to be registered where manufacture is carried on:

Address :
Telephone :
Fax :
E-mail :

I/we undertake to comply with all the terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place :
Date :

Signature
Name
Designation
Seal/Stamp of manufacturer or his authorized agent in India.

(Note:- In case the applicant is an authorized agent of the manufacturer in India, the Power of Attorney is to be enclosed)
*Delete whichever is not applicable.

Form43
(See rule 129 Cl)
Registration Certificate
Registration Certificate to be issued for import of cosmetics into India under Drugs and Cosmetics Rules, 1945

Registration Certificate No. ..... Date .....
M/s. ..... (Name and full Address of registere office) ..... having factory premises at ..... (full address has been registered under rule 129C as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of cosmetics, along with their brand names and pack size(s) and variants which may be imported under this Registration Certificate.
   (1)
   (2)
   (3)

3. This Registration Certificate shall be in force from ..... to .....unless it is sooner suspended or cancelled under the rule.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer, namely:-
   M/s.(name and full address) ..... who shall be responsible for the business activities of the manufacturer, in India in all respects.
5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard.

Place:.....

Date :.....

LICENSING AUTHORITY
Seal/Stamp

Conditions of the Registration Certificate

1. The Registration Certificate shall be produced by the authorised importer / distributer / agent as and when required by the licensing authority / regulatory authority.
2. The manufacturer or his authorised importer / distributor / agent in India shall inform the licensing authority forthwith in the event of any administrative action taken namely, market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any cosmetic pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed / sold or distributed.

   The dispatch and marketing of the cosmetic in such cases shall be stopped and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the

licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

2. PRTICULARS OF THE COSMETICS TO BE REGISTERED UNDER REGISTRAION CERTIFICATE:-

(a) Names of cosmetics along with their brands names, category, pack sizes and variants to be registered and meant for import into and use in India.

(b) Particulars of the manufacturing licenses / registration / marketing authorizations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses / marketing authorization / registration issued by the Regulatory Authority of that country.

(c) List of countries where marketing authorization or import permission for the said cosmetic has been granted.

3. CHEMICAL INGORMATION OF COSMETICS.-

(a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.

(b) Specification and testing method for testing of the cosmetic(s).

(c) Manner of labelling as per Drugs and Cosmetics Rules, 1945.

(d) Package insert (if any).

4. UNDERTAKING TO DECLARE THAT.-

(a) We shall comply with all the conditions imposed on the Registration Certificate for the import of cosmetics as required under the provisions of Drugs and Cosmetics rules, 1945.

(b) We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(c) We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.

(d) Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time.

(e) (We shall inform to the licensing authority, within 30 days in the event of any change in variants or in category or in manufacturing location or in labelling or in documentation of any of the cosmetic pertaining to the certificate to be granted to us.

(f) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals / regulatory restriction, or

cancellation of authorisation and / or "not of standard quality report" of any cosmetic pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the cosmetic is marketed / sold or distributed. The despatch and marketing of the cosmetic in such cases, shall be stopped and the licensing authority shall be informed immediately.

(g) We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.-

(h) We shall allow the licensing authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the licensing authority.

The information submitted above is true to the best of my / our knowledge and belief.

Place :
Date :

Signature of the manufacturer or
his authorized agent
Seal/Stamp"

INFORMATION

Antioxidants food supplements
Safety considerations and facts about Antioxidant therapy

Oxidation is a process which occurs in our body naturally or after it is exposed to certain chemicals or infections or tissue damages or exposure to radiations. Our body produces "free radicals," like peroxide radical, which are very unstable molecules, when they come in contact with a healthy tissue cell they attack on it and brings oxidative damages to its proteins and enzyme systems there by damaging the healthy cells. This process some time is a sort of chain reaction.

Free radicals are generated while our body metabolizes foods for energy and for storage. They are also generated when our body is exposed to tobacco smoke, radiation, and environmental contaminants and antigens and allergens . The damage thus caused by free radicals causes serious damages, also called as "oxidative stress," this oxidative stress has very important role in the developing diseases, like Rheumatoid arthritis, Alzheimer's disease, cancer, eye disease, heart disease, Parkinson's disease. Examples of such free radicals and highly corrosive and oxidative molecules which are produced in our body cells is as follows.

Highly oxidative molecules produced in cells are hydrogen peroxide (H2O2), ammonia, and nitrogenous products like creatinine and urea produced as a metabolic biproducts , hypochlorous acid (HOCl), free

radicals include hydroxyl radical (·OH) and superoxide anion (O2–) These oxidizing radicals can bring about oxidation in DNA proteins and Damage to DNA causes mutation and cancer , oxidation in body proteins and causes denaturation of proteins and enzymes, there by causes enzyme inhibition , vital body mechanisms are hindered or slowed down.

It is found in laboratory experiments that antioxidant molecules counter oxidative stress and its associated damage, but there is no clear evidence through "clinical trials" that an antioxidant treatment prevents serious diseases associated with oxidative stress. There is also a fear that consuming antioxidants in excessive doses may produce undesired effects.

The body has a capability to produce its own antioxidants and also it can get them from foods. vegetables and fruits, grain cereals, teas and nuts and legumes are best source of naturally occurring antioxidants they are found in abundance in them

Examples of antioxidants are as follows:

Anthocyanins, beta-carotene, catechins, coenzyme Q10, flavonoids, lipoic acid, lutein, lycopene, selenium, and vitamins C and E. glutathione, enzymes like catalase, superoxide dismutase and peroxidases Eating more antioxidant rich fruits and vegetables has showed some reduced risk of certain chronic diseases. However clinical trials with external supplement of antioxidant did not produce any benefits.

Safety considerations for antioxidants food supplements:

Antioxidants in foods and their supplements are considered safe, antioxidant supplements have not shown any adverse effects. However,

1)beta-carotene supplements in smokers may increase the risk of lung cancer

2)Supplements vitamin E can increase the risk of bleeding in certain individuals One should not use antioxidant supplements as a replacement for a healthful diet or medicines prescribed by your doctor or medical care or therapy.

Facts about Antioxidants:

There is no evidence so far supported by any clinical trial that use of an antioxidant supplement actually reduce the risk of all such diseases which are considered to be evolved due to toxic effect of oxidative process of free radicals, radiations. (From x-rays and TV and Computer monitors) Following is the only exception of clinical study where there is a positive result form the use of antioxidant treatment was provided at National Eye Institute where it was found that combining an antioxidant and zinc lowered the risk of developing advancements of age-related macular degeneration (AMD) with 25 percent in people who had intermediate AMD.

Antioxidants are substances which have more potential to get oxidised themselves than the surrounding medium where they get incorporated, be it a pharmaceutical dosage form or a dietary supplement. Antioxidants when incorporated in diet are considered to prevent oxidative cell damage diseases due to oxidative free radicals which results through natural body metabolism or after exposure to certain chemicals or radiations (Computer monitors, if you use it for long hours). Widely used antioxidant supplements include vitamins C and E, selenium, beta-carotene. Although observational studies have found that a diet

with high in antioxidant rich fruits and vegetables reduces the risk for chronic diseases remarkably, there is very limited proof to support that the use of antioxidant supplements to prevent disease.

Source: *Internet,*
www.whoguideline.blogspot.com,

Antibiotics - Definition and classification

Definition

Antibiotics is a group of drugs or substance or compounds which inhibits or completely stops growth or kills bacteria , fungi yeasts or protozoa, when present in very minute concentration , these are mostly metabolites produced by microorganisms which antagonises the microbial growth it self if present in very low concentration.

Most of the antibiotics are modified structurally to alter its pharmacokinetic or stability and antimicrobial properties so as to produce a most effective antibiotic, also most of them can be synthesized in laboratories.

Classification of Antibiotics

Aminoglycosides:
Works against infections caused by Gram-negative bacteria, such as Escherichia coli and Klebsiella specialy Pseudomonas aeruginosa. Effective against Aerobic bacteria.

Mode of Action:
Binding to the bacterial 30S ribosomal subunit (some work by binding to the 50S subunit), inhibiting the translocation of the peptidyl-tRNA Amikacin, Gentamicin, Kanamycin, Neomycin, Netilmicin, Tobramycin, Paromomycin, Streptomycin.

Ansamycins: Antitumor antibiotics Geldanamycin, Herbimycin

Carbacephem:
Mode of action: prevents bacterial cell division by inhibiting cell wall synthesis.

Loracarbef Carbapenems: Bactericidal for both Gram-positive and Gram-negative organisms and therefore useful for empiric broad-spectrum antibacterial

Mode of action: Inhibition of cell wall synthesisErtapenem, Doripenem, Imipenem/Cilastatin, Meropenem

Cephalosporins:
Mode of action: Inhibits the synthesis of the peptidoglycan layer of bacterial cell walls. Cefadroxil, Cefazolin, Cefalotin, Cefalexin, Cefaclor, Cefamandole, Cefoxitin, Cefprozil, Cefuroxime, Cefixime, Cefdinir, Cefditoren, Cefoperazone, Cefotaxime, Cefpodoxime, Ceftazidime, Ceftibuten, Ceftizoxime, Ceftriaxone, Cefepime, Ceftobiprole

Glycopeptides class of antibiotics:
Mode of action: Peptidoglycan synthesis inhibition Teicoplanin ,Vancomycin, Telavancin

Lincosamides class of antibiotics:
Mode of action: Blocks 50S subunit of and protein synthesis Clindamycin, Lincomycin

Macrolides class of antibiotics:
Mode of action: irreversible bloking of 50s

microbial ribosome, inhibit translation of tRNA and inhibit protien synthesis. Azithromycin, Clarithromycin, Dirithromycin, Erythromycin, Roxithromycin, oleandomycin, Telithromycin ,Spectinomycin

Monobactams class of antibiotics:

Mode of action: inhibits synthesis of peptidoglycan and cell wall Aztreonam

Penicillins class of antibiotics:

Mode of action: inhibits synthesis of peptidoglycan and cell wall Amoxicillin ,Ampicillin, Azlocillin, Carbenicillin, Cloxacillin, Dicloxacillin, Flucloxacillin, Mezlocillin, Meticillin, Nafcillin, Oxacillin, PenicillinG, PenicillinV, Piperacillin, Temocillin, Ticarcillin

Polypeptides class of antibiotics:

Mode of action: Inhibition of isoprenyl pyrophosphate, one of the molecule responsible for building peptidoglycan synthesis of bacterial cell wall
Bacitracin
Colistin
Polymyxin B

Quinolones class of antibiotics:

Mode of action: Inhibit the bacterial DNA gyrase enzyme and inhibit DNA replication. Ciprofloxacin, Enoxacin, Gatifloxacin, Levofloxacin, Lomefloxacin, Moxifloxacin, Nalidixic acid, Norfloxacin, Ofloxacin, Trovafloxacin, Grepafloxacin, Sparfloxacin, emafloxacin

Sulfonamides class of antibiotics:

Mode of action: Competitive inhibition of bacterial enzyme dihydropteroate synthetase,microbial nuclic acids synthesis is inhibited as microbial folic acid synthesis is inhibited. Mafenide, Sulfonamidochrysoidine, Sulfacetamide, Sulfadiazine, Silver sulfadiazine, Sulfamethizole, Sulfanilimide, Sulfasalazine, Sulfisoxazole, Trimethoprim, Trimethoprim-Sulfamethoxazole (Co-trimoxazole)

Tetracyclines class of antibiotics:

Mode of action: It inhibits binding of aminoacyl-tRNA to the mRNA-ribosome there by inhibiting translation process which is an inportant step in protein synthesis. Demeclocycline, Doxycycline, Minocycline, Oxytetracycline, Tetracycline

Rifamycin:

Mode of action: It inhibits DNA-dependent RNA polymerase prevents transcription and protein synthesis. Rifampin or Rifampicin

Amphenicols class of antibiotics:

Mode of action: Inhibits peptidyl transferase to 50S ribosome bacterial subunit chloramphenicol, Thiamphenicol, Azidamfenicol, Florfenicol.

Cycloserine: is antibiotic derived from cyclisation of serin

Mode of action: Inhibits enzyme alanine racemase and D-alanine ligase

What is antibiotic resistance, how antibiotic resistance is developed, how antibiotic resistance is counteracted

Antibiotics are substances which are produced by microorganisms , and are able to kill or stop growth of microorganisms completely , when they are present in minute concentrations. Antibiotics posses very complex stereo chemical structures which are highly susceptible for degradation or alteration by numerous factors like

enzymatic actions or effluxing out or removing out absorbed antibiotic from microbial cell , resulting in to nullification of microbicidal or microbistatic actions of these antibiotics. Enzymes or efflux pumps which brings about degradation or alteration or exclusion or removal of an antibiotic are mostly induced in to microbial or bacterial metabolic systems once these microbes come in contact with these antibiotic substances,this is one of the protective mechanism of microorganisms.These microorganisms then develop a resistance for a particular antibiotic with which these microorganisms were in contact , thus an antibiotic become little or less or inactive against these microorganisms.

Efflux Pumps in microorganisms:

This in an protective systems works with numerous feedback mechanisms of microorganisms, it can be defined simply as removing out any toxic substance out of microbial cell , this is a protenacious transport system of microorganisms , these proteins tag to a toxic substance in bacterial cell, here it is an antibiotic and remove them out of bacterial cell through active transport which involves supplementation of energy through break down of ATP (Adenosine triphosphate) molecule.

Neumerous drugs do develop drug resistance due to the phenomenon listed above.

How antibiotic resistance is counteracted

So far there is not a single drug available which has proved to be effective in clinical trials that it can prove to be effective as efflux modifier and help antibiotic to carry out the desired action.

There are some enzyme inhibitors currently in use which are listed below

Beta-lactamase inhibitors:

Are the class of drugs which are given in conjugation with betalactam antibiotics. These molecules do not have any antibiotic activity but they enhance the antimicrobial activity of beta-lactam antibiotics .

It is considered that betalactam antibiotics like penicillins and cephalosporins develop resistance as some microorganisms produce an enzyme betalactamase which causes breakdown of this betalactam ring in betalactum antibiotics this betalactum ring is a peculiar characteristic of betalactum antibiotics.

1. Clavulanic acid and its salt with potassium, potassium clavulanate is formulated along with amoxicillin.
2. Sulbactam is formulated with cefoperazone and ampicillin . sulbactum binds with betalactamase irreversibly there by protecting actual antibiotics from enzymatic degradation.
3. Tazobactam is also a betalactamase inhibitor it is formulated with piperacillin

Source: *Internet,*
www.whoguideline.blogspot.com

Why betalactam antibiotics require separate manufacturing area in a pharmaceutical manufacturing company?

Chemistry behind the allergic reactions and mode of action of betalactum antibiotics To avoid cross contamination of other products with betalactam antibiotics because

A. The betalactam antibiotics may cause anaphylactic shock and anaphylaxis or may cause life threatening allergic reactions.
B. The betalactum antibiotics molecules mode of action is more or less cytotoxic as discussed below.
C. Untoward consumption of betalactam antibiotics as contaminant in other product in smaller amount may result in development of untoward Drug Resistance or antibiotic Resistance for betalactam antibiotics and whenever desired, betalactam drugs may not prove effective in individuals who got betalactam antibiotic in contamination.

The question is very simple and the answer too is very simple but we will like to provide you a answer to your question which is based up on chemistry of the betalactum antibiotic molecule.

Hence first one should know how a betalactam antibiotics act against microorganisms

What is the mode of action of betalactum antibiotics?

1. Acylation of proteins
Betalactum antibiotics contain a betalactum ring; this ring is a chemically active portion of the betalactam antibiotics as it takes part in reaction in vitro to bring about acylation of amino acids in proteins and enzymes. Acylation at a terminal end in protein amino acid result in termination of polymerization process in protein synthesis specially the cell wall proteins.

2. Generation of Free radical Iminium ions which are cytotoxic to bacterial enzymes and proteins
Betalactam ring in presence of certain PH range get converted in to a very unstable free radical which is very cytotoxic to microorganisms cellular proteins and enzymes, Iminium ion is very active and cytotoxic moiety which takes part in numerous reactions which are responsible for cytotoxic effects.

Why a allergic reaction occurs in penicillin drugs

As discussed above penicillins are betalactam antibiotics and about 7% to 8 % of individuals in world are allergic to penicillin's and the allergy may be a life threatening for an individual Because in vitro penicillin get reacted with human proteins to form a penicilloilproteins these proteins are synthesized as a result of acylation reaction over the human proteins and they are now new proteins after acylation and recognized as antigens in human immune system, they trigger a sequence of immunological responses by developing antibodies against these penicilloilproteins which further reacts to form antibody and antigen complexes , these reactions are sever and may be harmful to an individual.

Source: *Internet,*
www.whoguideline.blogspot.com
Tuesday, July 20, 2010

NEWS

Abbot Labs is new leader of Indian drug market

India's drug retail market grew 19.6% in the first six months of the year, headed by new leader American company Abbott Laboratories, as foreign drugmakers strengthen their dominance among the top 10 brands sold in the country.

By June end, Abbott held a market share of 7% followed by domestic heavy weight Cipla that controlled 5.3% of the market, according to market research firm ORG IMS. The acquisition of Mumbai-based Piramal Healthcare's domestic formulation business, with a 4.2% market share, in May, helped Abbott dislodge long time leader Cipla.

Ranbaxy Laboratories, owned by Japan's Daiichi Sankyo, having a market share of 4.83% is ranked third, followed by UK's GlaxoSmithKline that controls 4.28% of the market. Ahmedabad-based Zydus Cadila is fifth with a 3.8% market share. In June 2008, Japan's Daiichi Sankyo had bought Ranbaxy catapulting it to the second position then.

Cumulative sales for the six months were around Rs 21,895 crore. Last year, the local drug retail industry rose 17%, making it one of the fastest-growing markets globally. This is one of the reasons attracting global drugmakers to India, as growth in developed markets like the US and several European countries are either stagnant or in single digits.

Among brands, Abbott's acquisition of the country's second-largest selling brand cough syrup Phensedyl (Piramal Healthcare) means the top-seven brands sold in the country are owned by foreign drugmakers. Pfizer's cough syrup, Corex, is the most sold medicine in the country with an annual sale of about `204 crore. Phensedyl ranks just a shade lower at Rs 203 crore. The list of top sellers mainly consists of antibiotics and vitamins, besides cough syrup.

A series of buyouts by foreign heavy weights, including Ranbaxy and Piramal Healthcare (domestic formulation business) has also resulted in foreign MNCs taking three slots among the country's top-five drugmakers. Their market share has grown to about 25% from 15% in just two years.

Source: *The Economic Times, 9th August, 2010*

Consumers vulnerable to fleecing

Homemaker Sumathi Ramanathan (name changed) used to get her drugs delivered at her doorstep from a popular medical store in her neighbourhood in Kotturpuram. The drug store was at her back and call, delivering medicines quickly, even late in the evening.

Last month, she ordered for a tablet to cure the fungal infection on her feet and bought three strips for Rs 120. Recently, Sumathi picked up the same tablet from a different shop. She was shocked to know that her 'favourite' medical store had charged 400 per cent more than the MRP.

She was unable to fight her case, as the druggist clearly refrained from mentioning the quantity of the medicines supplied while billing.

"One strip of the tablet costs Rs 10 in other medical stores. But my regular medical store charged me Rs 40 per strip. I was stunned and alerted the drug control department," she said. Like Sumathi, scores of patients pay a higher price for their medicines unknowingly.

Drug Control Director Mr. M. Bhaskaran said 'money power' combined with the irresponsibility of pharma traders were the major reasons for the exorbitant price of drugs. "The amount of money spent on medicines burns a big hole in the pocket of a sick man. Several pharma companies are happily making money by charging higher prices. Though the same drug is available for a cheaper price with a different name, medical stores are interested in selling only drugs that are expensive. It is the responsibility of the patients to check the MRP," he said.

Prof V. Ravichandran, Vice-President of the Tamilnadu Pharmacy Council, said the government should work out a fixed price for drugs without affecting the manufacturers. "We want to sell drugs at affordable rates. But the government should check on the global pharma market and fix the prices before blaming us for selling at a higher price," he said.

Source: *Deccan Chronicle, 11th August, 2010*

Drug store staff offer expert advice and pills

From irregular heartbeats to loss of eyesight and liver failure, a host of drugs that are banned internationally for dangerous side-effects are stocked up in medical stores across the country. Despite alarming chain emails making the rounds, which list out some of the brand names of the drugs and the disaster they can cause to the system, many people continue to try self-medication without consulting doctors.

"On a stressful day at work, I'd rather run to the nearest pharmacy and buy a strip of tablets to fix my headache than suffer the pain or visit a doctor," says Elizabeth K, an HR professional. "In no other country do medical stores sell even basic analgesics or anti-histamines over the counter, without a prescription," says Dr S. Elango, former director of public health. "There are many pharmacies in the state which do not even employ pharmacology graduates. Customers treat medical shop staff like doctors, and explain their symptoms to them, expecting these clerks to prescribe and hand over medicine," he says.

Narcotics are the only drugs which the government tracks very carefully, and this system should be implemented for medicine that is available in drug stores, feels a senior doctor. But this is easier said than done. "There are educated people who demand the chemist for OTC drugs to get temporary relief from their problems. There is also a larger group of people who do not go to doctors, either because they don't have access to them, or because they cannot bear the cost of consultation," he explains, pointing out why regulating sale of OTC drugs could backfire. "Theoretically, even subtle changes in composition from brand to

brand can be very dangerous. But we cannot become strict with implementing any rules all of a sudden," he says.

The only way out, at least for those who are ready to grab a pill every time they sneeze or rush to the loo more than once, is to understand that no drug is safe. "In western countries, several drugs have been withdrawn after they have passed the clinical trials and have entered the market, as the authorities have found adverse reactions when a larger population is exposed to the drug. At least the surveillance after releasing it for sale should be monitored properly," the doctor explains.

Source: *Deccan Chronicle, 11th August 2010*

Govt. stand on alternative medicine still ambiguous

Although the Madras high court has held that registered Siddha, Ayurveda, homeopathy and Unani practitioners can practice surgery, the government's stand on the issue smacks of ambiguity while dealing with alternative systems of medicine, which it seeks to promote even while claiming to check illegal practitioners. The recent crackdown had seen several traditional practitioners being booked for prescribing allopathic drugs.

Taking a different view in February, the director of medical and rural health services told the court that unani practitioners prescribing allopathic drugs would amount to illegal practice and they were liable for legal action. The syllabi of unani and MBBS were not similar and persons who did not have a valid MBBS qualification could not be registered in the Indian Medical Council Act register, he said.

The Siddha Graduates' Association had filed a contempt petition against the director-general of police, stating that practitioners of the Indian medicine system were being arrested despite an April 7, 2006, order of the court restraining authorities from interfering with the practice of members who held valid registration certificates.

When the matter was taken up earlier this week, the government furnished a copy of the June 19, 2010, circular, which admitted that the police had inspected clinics of several practitioners of Siddha, Ayurveda, homeopathy and Unani and even arrested some of them during a drive against quacks. Making it clear that these registered practitioners were free to do surgery on the basis of their "training and teaching", the circular said cases against doctors already arrested would be reviewed.

Recording the details, Justice FM Ibrahim Kalifulla said: "It is imperative that no proceedings can be initiated against any of those registered practitioners in Siddha, Ayurveda, homeopathy and Unani, who are eligible to practice the respective system along with modern scientific medicine including surgery, gyanecology and obstetrics, anaesthesiology, ENT, ophthalmology, etc. If any action had been taken against such medical practitioners, it is needless to state that such action should be dropped forthwith..."

Reacting to the latest order, state Health Secretary V. K. Subburaj said they were just making use of the provisions in the Act. "But this is allowed only for those who attended colleges and underwent training for surgeries. Those who have been registered as traditional practitioners will not be allowed to do surgeries," he said.

Indian Medical Association general secretary T. N. Ravishankar, however, argued that it was impossible for the state to regulate this. "Who will monitor this? In any case, when a gynaecologist cannot practice cardiology, how can the state allow Siddha doctors to practice any other system? Doesn't it defy logic?" Ravishankar asked, stating that they would go on appeal.

Source: *The Times of India, 30th July, 2010*

More medicines may come under price control

The high-level parliamentary body has asked the government to increase the number of medicines under price control cap prices of patented drugs and prevent global Pharma companies from buying Indian firms to ensure that the cost of health care remains low for the consumer. The parliamentary standing committee on health expressed disappointment at the gradual reduction in the number of drugs under price control from 347 in 1,1979 to just 74 at present despite high prices of medicines in the country.

"The committee is therefore convinced that there is no alternative but to include more essential and life saving drugs under price control," the committee headed by Amar singh said in a presentation to the Rajya Sabha on Wednesday. The committee's recommendations are advisory and not mandatory but the government can take a cue from the suggestions. The proposed policy in Pharma pending since 2006 has also proposed to bring 354 essential drugs under price control. Drug makers are opposed to such plans saying that there is enough competition in the market that has made drugs in the prices lowest in the world.

For drugs that are outside price control there is a need to cap the profit margin, the committee said. Since similar system is already adopted in others sectors such as electricity, taxi and bus fares besides insurance premium, drug price regulator National Pharmaceutical Pricing Authority (NPPA) can do the same for drugs, it said.

Pricing of new patented medicines are outside the jurisdiction of NPPA and the committee has urged the government to plug this loophole as it feels this gives a free hand to MNCs to launch their brands at an exorbitant price in local market.

Over 60 medical shops booked in state for selling expired drugs

The state Directorate of Drugs Control has booked more than 60 cases against medical shops across the state since April for various offences, including sale of expired drugs and sale of drugs, including abortion pills, without prescriptions, violating the Drugs and Cosmetics Act, and Rules, state Health Minister MRK Panneerselvam said. Sample drugs worth Rs. 2 lakhs, meant to be given to doctor, were seized from the

residence of a medical representative, who was caught selling them, the minister said in an official release.

On July 24, the drugs inspectors raided shops in Tripur to check on abortion pills-MT Pill and Unwanted Pills-being sold without prescriptions of registered Medical Practitioners.

Abortion pills are schedule H drugs that have to be sold only on prescriptions by a doctor as it can led to serious health problems that can sometimes prove fatal.

During the inspection, 17 medical shops in Tripur were found selling these drugs over the counter.

It is a dangerous trend as women have no conformation about the pregnancy. The women has to ensure that the foetus is in womb and not in the fallopian tubes. If the foetus has settled in the tubes, there are chances of the foetus growing there. The tubes can rupture, cause severe bleeding and sometimes even death, "says gyneacologist, Dr. Priya Selvaraj. Doctors also add that the pill induces severe bleeding and the woman has to be screened after seven days to ensure that the uterus is emptied out.

"Else it can cause a series of problems including foetal deformation, "she said.

The drug inspectors initiated legal action under Drugs and Cosmetic Act and Rules against 16 drug stores across the state. On July 23, drug inspectors raided a city-based medical shop and found they were selling expired drugs with tampered lables.

"They had violated a series of rules. They were selling drugs without prescriptions. Though the rules make it mandatory for all shops to employ a pharmacist, they did not have anyone qualified at the shop during the business hours. Worse, they did not even maintain registry, "said a senior drug inspector.

Source: *The Economic Times, 1st August, 2010*

EVENTS

School of Pharmaceutical Sciences, Vels University, Chennai

Vels University has signed a memorandum of understanding (MoU) with major pharmaceutical companies on September 23, 2010 at Vels University, Chennai. The leading companies like Tablets India Limited, Edict Pharmaceuticals, Kniss Laboratories (P) Limited and Herbal Galanicals signed MOU with Vels University. These industries will provide training programs for the faculty members of the university and students. They mutually extend their expertise and facilities for development of new formulations and sort out the problems in their production. The MOU was signed in the presence of Tamilnadu Pharmacy Council President Prof. K. Chinnaswamy, Chancellor of Vels University Dr. Ishari K. Ganesh, Vice-Chancellor Prof. Dr. S. Ramachandran, Pro-Chancellor Mr. S. Kamalakannan, Registrar Dr. P. Govindarajan and Dr. V. Ravichandiran, Director, School of Pharmaceutical Sciences, Vels University

College of Pharmacy, Madras Medical College, Chennai

A refresher course for pharmacists was conducted by the Department of Pharmaceutics along with the Tamilnadu Pharmacy Council on 02-07-2010 at Madras Medical College, Chennai. Dr. Mohanasundaram, Dean, Madras Medical College presided over the inaugural function. Thiru. M. Bhaskaran, Director, Drugs Control Department, Government of Tamilnadu was the Chief Guest and delivered the keynote address.

Dr. N. Narayanan, Joint Director of Medical Education (Pharmacy), Thiru. T. Ilango, Registrar, Tamilnadu Pharmacy Council, Dr. A. Jerad Suresh, Principal i/c College of Pharmacy and Dr. A. Sundaram, Vice-Principal offered their felicitation.

Thiru. G. Selvaraj, Assistant Director, Drugs Control Department delivered a lecture on Drugs and Cosmetic Act and Rules. Dr. M. Nappinnai, Professor, C. L. Baid Metha College of Pharmacy explained about the Stability of Pharmaceuticals, its implications, prediction of shelf life and stability testing in Indian conditions. Dr. Ilavarasan, Assistant Director, Captain Srinivasa Murthi Drug Research Institute for Ayurveda and Siddha delivered a lecture on "The Role of Pharmacists in Management of Diabetes and Cardio vascular Diseases". Mrs. Daisy Chellakumari, Tutor, College of Pharmacy explained about Newer Drug Delivery Systems. About 160 pharmacists participated in the refresher course.

Faculty of Pharmacy, Sri Ramachandra University, Porur, Chennai

Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Sri Ramachandra University, Porur, Chennai organised a one day workshop on ***"Practicum on HPLC"*** in collaboration with Spinco Biotech Pvt. Ltd., Chennai on 4th September 2010. Dr. C. Uma Maheaswara Reddy, Principal welcomed the gathering. Dr. K. V .Somasundaram, The Dean of Faculties, Sri Ramachandra University inaugurated the function. Mr. V. Namasivayam, Regional Service Manager, Spinco Biotech Pvt. Ltd., delivered a special lecture on ***"Principle and Instrumentation of HPLC"*** followed by practical training on handling HPLC instrument. 20 faculty members from pharmacy colleges of Tamilnadu participated in the workshop. Dr. K. Chitra, Prof. and Head, gave a vote of thanks.

PARLIAMENT QUESTION - ANSWERS

RAJYA SABHA

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No. 2505
Answered on 17.08.2010

SALE OF SPURIOUS DRUGS
2505 Shrimati Bimla Kashyap Sood

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-
to reply to Starred Question 458 given in the Rajya Sabha on the 27 April, 2010 and state:

(a) whether 255 persons involved in sale of spurious drugs were arrested and the value of drugs recovered from them over nearby past three years is estimated at Rs. 171001667/- ;

(B) if so, the penalty and punishment awarded to all the nabbed persons and whether their licences were also cancelled;

(c) whether the Ministry has set up a special team or committee to check such incidents so that sale of spurious/substandard drugs could be curbed in future; and

(d) if so, the details of the committee/team constituted, State-wise?

ANSWER

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRIDINESHTRIVEDI)

(a):Yes.

(b): In case licensed manufacturer are found to be involved in activities relating to the manufacture of spurious drugs their licenses are immediately suspended for further investigations and if necessary, prosecutions are launched in various courts of law. The punishments are awarded by the courts only after completing the legal procedures in each case.

© & (d): The manufacture of spurious drugs is an undercover activity and can only be curbed through vigilance, raids and following the leads available in such cases. There is already a well laid mechanism/ set up in the country in the form of the Drugs Control Departments of the State Governments and the Central Drugs Standard Control Organisation under the Drugs Controller General (India) whereby an effective check/vigilance is maintained to curb such activities. The Government has also announced a Whistle Blower Scheme to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No 2517
Answered on 17.08.2010

TAKEOVER OF INDIAN PHARMA COMPANIES BY FOREIGN COMPANIES.
2517 Shri T. K. Rangarajan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) the details of Indian pharmaceutical companies taken over by foreign companies in the2009-10;

(b) whether there is any increase in the price of the drug produced by these companies after the takeover;and

(c) if so, the steps taken to control the prices of drugs increased subsequent to these takeovers?

ANSWER

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRIDINESHTRIVEDI)

(a)Some Indian pharmaceutical companies including M/s Piramal Healthcare have been taken over by foreign companies.

(b) to (c): The National Pharmaceuticals Pricing Authority (NPPA) fixes/revises the prices of 74 bulk drugs, specified in the First Schedule of Drug Prices Control Order (DPCO), 1995 and the formulations containing any of these Scheduled drugs. The prices of Scheduled formulations are fixed or revised in accordance with the paragraph 7 of the DPCO, 1995. No one can sell any Scheduled drug/formulation at a price higher than the price fixed by NPPA. Prices of Non-Scheduled formulations are fixed by the manufacturers themselves keeping in view the various factors like cost of production, marketing/selling expenses, R&D expenses, trade commission, market competition, product innovation, product quality etc. However, NPPA monitors the prices of all formulations based on the reports of ORG IMS and the information furnished by the individual manufacturers. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of formulation in public interest. Monitoring of prices is an on-going process.

SPURIOUS DRUGS IN THE MARKET GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE RAJYA SABHA

QUESTION NO 2505
ANSWERED ON 17.08.2010
1737 Prof. P. J. Kurian

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to satate :-

(a) Whether it is a fact that a number of spurious and out-dated drugs are being sold in the country;

(b) if so, the details thereof;

(c) the number of cases registered in this regard and convictions, if any; and

(d) what steps Government proposes to take for more stringent action in such cases?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE (SHRIDINESHTRIVEDI)

(a) to (c): The manufacture and sale of spurious drugs is a clandestine activity and sporadic cases of spurious drugs are detected in various parts of the country.

Three statements giving details regarding the spurious drugs as provided by the State Drugs Controllers including the number of people arrested and cases registered in the last three years 2007-2008, 2008-09 and 2009-2010 are at annexure I,II and III respectively. A Statement giving details of cases of sale of out dated i.e. date expired drugs as has been detected in Tamil Nadu, Mizoram, Tripura and Assam is at annexure-IV.

(d): Following measures have been taken by the Government to check the menace of spurious drugs in the country:

1. The Drugs and Cosmetics Act, 1940 has been amended under Drugs & Cosmetics (Amendment) Act 2008, whereby more stringent penalties for manufacture and trade of spurious and adulterated drugs have been provided. Certain offences have been made cognizable andnon-bailable.

2. A Whistle Blower Scheme has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No. 950
Answered on 03.08.2010
PREVENTING USE OF SPURIOUS AND ADULTERATED DRUGS .
950 Shri Rajkumar Dhoot

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-
(a) whether it is a fact that many units manufacturing spurious and adulterated drugs and medicines of popular brands have been unearthed since 1 January, 2009 in different parts of the country;

(b) if so, the details thereof and the actions, taken against the culprits;

(c) whether Government would publicize details of such drugs and medicines with their source of supply for information of hospitals, chemists and general public to prevent their use; and

(d) if not, the reasons therefor?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): The information as furnished by

the State Drugs Controllers in respect of spurious and adulterated drugs detected in their states during the year 2009-10 is annexed.

© & (d): The manufacture and sale of spurious drugs is a clandestine and localized activity indulged in by anti social elements. A recent survey carried out by Central Drugs Standards Control Organisation (CDSCO) on the basis of the statistical principles provided by Indian Statistical Institute (ISI), Hyderabad to assess more accurate extent of spurious drugs in the country has revealed that the extent of spurious drugs is about 0.045%. As the label of spurious drugs indicate the name and particulars of the

manufacturers of spurious drugs, wide circulation of the particulars may result in creating unnecessary scare about the quality of genuine formulations otherwise available in the market.

UNSTARRED QUESTION NO 5055
ANSWERED ON 27.08.2010

PHARMACEUTICAL INDUSTRY

5055 Shri MAGUNTA SRINIVASULU REDDY RAJAGOPAL LAGADAPATI

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:-

(a) whether the Indian Pharmaceutical Industry is going through a transformative phase with a number of local firms selling out to Multi National Companies (MNCs);

(b) if so, the details thereof;

© whether some MNCs have launched campaign against the Indian Pharmaceutical Industry;
(d) if so, the details thereof;

(e) whether the Government has made any complaint to the World Intellectual Property Organisation (WIPO) in this regard; and

(f) if so, the details thereof alongwith further measures taken by the Government to counter the said campaign by MNCs?

ANSWER

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) to (d): The Indian Pharmaceutical Industry is undergoing rapid expansion. Government is aware of events relating to mergers and acquisitions of Indian Pharmaceutical companies with Multi National Companies. The Department of Pharmaceuticals has taken steps to counter various MNCs campaign specially on IPR issues with the help of FICCI, Pharmexcil, domestic Pharma associations and Indian missionsabroad.

(e):No.

(f): Does not arise.

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