Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 28 **Oct. - Nov. - Dec. 2015**

CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

First of all we wish all our readers a very Happy New Year 2016.

We are happy to publish the 28th issue of Pharma Web Newsletter for Oct – Dec 2015. During this quarter, we wish to inform all our readers that our **"Pharma Knowledge and Training Institute" (Finishing School)** has conducted 3rd "Industrial Training programme" for fresh Pharma graduates during September – October 2015 for a period of one month on the subject of "QC & QA Management". The response to this training programme was enormous from the Pharmacy colleges, and more than 60 pharmacy students participated.

The following articles are published in this issue:

a. Good Laboratory Practices by **Mr. Satish H Joshi,** Pharma Consultant, SHJ Consulting Services, Chennai.

b. Responsible Use of Antibiotics Saves Lives by **Dr. S. Sriram,** Prof & Head, Department of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore.

We have published two Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules.

a. Draft Rules pertaining to definition of Clinical Trials as well as certain amendment in Schedule Y

b. A draft Notification containing revision of fees structure for import, Manufacturing, Test Licence and other licences under Drugs and Cosmetics Act & Rules

c. A letter issued by DCGI forming the stake holders to apply import registration through online.

Our Trust sponsored the National Pharmacy Week Celebration, celebrated by IPA, TN Branch.

Dr. T. K. Ravi, Principal, College of Pharmacy, SRIPMS, Coimbatore, awarded as the Pharmacist of the year during the function. **Dr. S. Sriram,** Professor & Head, Department of Pharmaceutics, SRIPMS, delivered the lecture on the theme of **"Responsible Use of Antibiotics Saves Lives".** Our Trust has also instituted various awards like Scholarship for M. Pharm & Pharm D students, Essay competition for B. Pharm students and meritorious students of B. Pharmacy from The Dr. MGR Medical University.

Important news items appeared in national news papers on various technical issues are also published in this issue.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,

R. Narayanaswamy

Chief Editor

ARTICLES

GOOD LABORATORY PRACTICES

by

Mr. Satish H Joshi,

Pharma Consultant, SHJ Consulting Services, Chennai

(Lecture Delivered on 19th September 2015, during the Training Program on Quality Management,conducted by TNPSWT)

GLP

The three principle under GLP procedure are...

- Accuracy – Without which both time and work will be wasted.
- Diligence – The caring attitude which binds honesty and accuracy together.
- Validation - Every activity must be validated to ensure that it achieves its intended purpose.

GLP

- Regulatory agencies are government bodies responsible to ensure that the drug substance / products are fit for their intended use. They inspect / Audit manufacturers/testing laboratories to ensure that the drug substance/drug products are being manufactured as per cGMP regulations.
- CDSCO – Central Drugs Standard Control Organization (Indian FDA)
- USFDA – United States Food And Drug Administration **(CFR - Code of Federal Regulations Title 21)**
- MHRA – Medicines and Healthcare Products Regulatory Agency (European Countries) **(MHRA Guidelines Volume 4)**
- TGA – Therapeutic Goods Administration (Australia)
- MCC – Medicines Control Council (South Africa)
- TPD – Therapeutic Product Directorate (Canada)

GLP

Number of countries require the manufacturers to perform laboratory studies on such products for their properties and safety and to submit the results of these studies to government authority/regulatory authorities for the assessment of potential hazards to human health and the environment and have passed legislation to that effect.

GLP

- Good Laboratory Practices has been made as law by introducing it as Schedule L-1 which is a New Schedule under Drugs and Cosmetics Rules, 1945 vide Gazette notification no GSR 780 (E) 10-11-2008 with effect from 1-11-2010. Consequent to this amendment, Rule 74, 78 and Rule 150E of the Drugs and Cosmetics Rules, 1945 have been amended. It involves a number of good practices in the Quality Control laboratory which are to be undertaken to carry out an analysis with a defined degree of Accuracy & Precision.

GLP

- Good Laboratory Practices(GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

GLP

- **The principle of Good laboratory practice (GLP) :** to promote the development of quality and validity of test data used for determining the safety of chemicals, Pharmaceuticals, Food, Cosmetics etc.
- Since raw materials, packaging materials, intermediates and finished products are ultimately released based on the analytical results generated in the Quality Control Laboratory, Accuracy, Precision and Reliability of these results are of paramount importance.

GLP

- Quality Control Laboratory:
  Comprises of major sections like:

  - Raw Material testing
  - Packaging Material testing
  - In-process/ Finished product
  - Stability testing
  - Microbiological testing
  - Laboratory Services

In addition arrangements shall be made for calibration of instruments, Preparation volumetric and test solution, Qualification of analyst and training.

GLP-**Schedule-L1**

1. Premises
2. Personal
3. Equipments
4. General requirements
5. Chemicals & Reagents
6. Good House Keeping and Safety
7. Maintenance, calibration, and validation of equipments
8. Reference materials

GLP-Schedule-L1

9. Microbiological cultures
10. Quality system
11. Internal quality system audits
12. Management review
13. Standard Operating Procedures
14. Protocols and Specifications archive
15. Raw data
16. Storage and archival

GLP

- Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.

GLP

FACILITIES
- General
- Designed to suit the operations

- Sufficient space to avoid mix-up and cross contamination

- Separate QC laboratory area from production area

- Separate Microbiology laboratory from chemical and instrumental laboratory

- Separate room for sensitive equipments

GLP

- Adequate space for sampling, reference standards, reagents, glassware, records and reports

- Separate air handling units for microbiology department

- Adequate lighting, temperature, humidity and ventilation

- Adequate space for production and packing areas

GLP

- FACILITIES
- Laboratory Environmental Monitoring Program
- Have Environmental monitoring program applicable to the specific laboratory functions.

- Monitor environmental parameters such as room temperature, relative humidity, airborne viable particles on a regular basis

- Document and investigate any excursion/out of limit

GLP

- FACILITIES

Laboratory Room Pressure Differential

Rooms within a laboratory that are dedicated to performing product sterility testing are maintained at a positive room pressure differential to the main laboratory room

- Laboratory Illumination and Personnel Visual Acuity / Color Blindness

Adequate illumination to assure the integrity and validity of tests that requires of visual determinations (i.e. end point titration color changes, visual evaluations, etc.).

GLP

- EQUIPMENT
- GMP REQUIREMENTS FOR EQUIPMENT
- Qualifications (DQ, IQ, OQ and PQ)
- Master list and unique identification number
- Training to the user for handling and maintenance
- Availability of operating and calibration procedures
- Well recorded preventive maintenance system.
- Control over computer or related systems.

GLP

Storage Area for Lab Chemicals, Glass Apparatus & Miscellaneous Items:

There should be an adequate area with proper demarcation and proper temperature control wherever required for storage of laboratory chemicals, solvent, glass apparatus & miscellaneous items.

In addition to these, there should be adequate arrangements for all types of services like vacuum, compressed air, nitrogen, potable water, purified water, ultra-pure water etc. in different sections of Q.C. Lab.

GLP

- Development of suitable working Standard from available active raw materials with the help of these primary standards.
- Identification and Storage of working standards with expiry date, retest date and other appropriate information.
- Documentation of all information regarding these primary standards and working standards.

GLP

Reference microbial cultures

- Procurement from Central Drugs Laboratory, Kolkata; National Collection of Type Culture (N.C.T.C.) U.K. and American Type Culture Collection (A.T.C.C.) U.S.A. wherever required.
- Proper Maintenance in the microbial lab as per respective pharmacopoeia.
- Proper documentation.

GLP

All analytical Reagents and Chemicals should be of analytical reagents grades of suitable manufacturer. These should comply with the specification for reagents given in different pharmacopoeia. The specification of the reagents required must be mentioned clearly in the test method.

GLP

- Glassware usage:
- Two types of glassware used in laboratory
- Class A and Class B
- Class A: with test certificate, as per specification laid down by B.I.S.
- Class B: as B.I.S.
- Class A are to be used for Work of the highest accuracy like standardization of volumetric solutions & Class B for routine work. Cleanliness of glassware should be ensured before use and periodic validation in this respect are to be done.

GLP

All standard solutions (reference standards and volumetric Standards) and reagents solution must have proper labels indicating name, strength, date of preparation, date of expiry and storage conditions. Proper documentation having details of preparation of these solution are to be maintained chronologically.

GLP

- Calibration:

  Calibration is the comparison of the performance of a measuring equipment / instrument with that of standard equipment / instrument.

  In a Quality Control lab, all equipments and instruments which are directly or indirectly used for measurement are to be calibrated periodically.

GLP

- Calibrations are done in-house or by external laboratories;
- Some measuring equipments / instruments like pressure gauge, thermo dials, glass thermometers, wet and dry bulb hygrometers, balances etc. can be calibrated with the help of an NABL accredited external agency.
- Some measuring instruments like UV VIS Spectrophotometer, Polarimeter etc can be calibrated internally using methods described in pharmacopoeia.

GLP

- All laboratory test apparatus must be maintained, checked & calibrated to ensure accurate and repeatable results.
- The SOP defines how the equipment is calibrated before any testing activity and the method of operation during the process and its frequency.

GLP

Important questions to be answered for any analytical instrument

- What is the equipment being used for?
- Is the instrument within specification and is the documentation to prove this available?
- If the instrument is not within specifications, how much does it deviate by?
- If the instrument is not within specifications what action has been taken to overcome the defect?

GLP

Important questions to be answered for any analytical instrument

- Can the standards used to test and calibrate the instrument be traced back to national standards?
- What is the equipment being used for?
- Is the instrument within specification and is the documentation to prove this available

GLP

- Important questions to be answered for any analytical instrument

- If the instrument is not within specifications, how much does it deviate by?
- If the instrument is not within specifications what action has been taken to overcome the defect?
- Can the standards used to test and calibrate the instrument be traced back to national standards?

GLP

Analyst Qualification:

- Some acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established for each analyst.
- Qualification can come from education, experience or additional trainings, but it should be documented
- Sufficient people
- Requirements of certification vary

GLP

Documentation and Maintenance of Records

- Maintenance of all records provide documentation which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results.
- General guidelines followed in regulated laboratories is to maintain records for at least five (5) years
- Length of time over which laboratory records should be maintained will vary with the situation

GLP

- Analytical Method Validation:
- All non Pharmacopoeial analytical methods having tests for identity, impurity / impurities & purity are to be validated properly before use in respect of –

1. Accuracy
2. Precision
3. Specificity
4. Linearity and Range
5. Limit of Detection
6. Limit of Quantitation
7. Robustness and
8. Ruggedness

- (as applicable for each individual method).
- For detailed methods of validation ICH guidelines may be referred.

GLP

- Usual Document and records with which Q C Laboratory has to deal with are –
  - Specification
  - Test Procedure
  - Standard Operating Procedures
  - Certificate of Analysis with relevant Test Protocols
  - Sample Register
  - Register for Reference Standards & Reference Cultures
  - Calibration Records
  - Validation Records
  - Training Records

GLP

- Usual Document and records with which Q C Laboratory has to deal with are –
  - Records for Retained samples (Both finished products & active raw materials)
  - Records pertaining to the preparation of solutions of reference standards, volumetric solutions and other reagents.
  - Log book for instruments & equipments.

- All documents are to be reviewed periodically and updated whenever required. Records should be maintained in such a manner that these are always traceable. If required help of electronic data processing system may be taken.

GLP

Safety:

- In the Quality Control Laboratory, one has to handle a no of hazardous, poisonous and inflammable chemicals and also pathogenic organisms. Hence the adoption of proper safety measure and use of safety devices are of paramount importance.
- The use of mask, gloves, face shields, aprons, gumboots etc. should be made compulsory in the handling of corrosive chemicals. There should be adequate fire fighting arrangements in the laboratory and personnel should be given proper training for fire fighting.
- Training for other safety measures should be imparted regularly and records of these training should be maintained. Microbial residues should be regularly destroyed by autoclaving and records maintained.

GLP

Availability of safety manual

- Safety audits at frequent intervals and corrective actions
- Provision of Eye washing station, Emergency shower and fire extinguishers at appropriate locations
- First aid facilities in place and sufficient number of staff trained in first aid

GLP

- Compressed Gases/Gas Generators
  Locate preferably outside the laboratory
- Transportation trolley (with chaining feature) for compressed gas cylinders transportation.
- Gas generators are an acceptable replacement to compressed gas cylinders. Gas generators s hall be installed and qualified as per protocol

GLP

- Laboratory Fume Hoods
- Verified on a regular basis to assure the adequate air exhaust velocity is present when the system is turned on.

  Note: If the fume hood has a differential pressure (magnehelic) or exhaust performance indicator, the requirement to perform this specific checks can be eliminated.
- Do not use for storage of laboratory equipment, glassware, flammable reagents, or other laboratory materials or equipment.

GLP

PERSONNEL AND TRAINING

- Sufficient qualified personnel to carry out all the tasks for which it is responsible
- Clear job description of the individual and understanding of it
- Written, approved training policy and program and trainings as per calendar
- Trainings include induction training, SOP trainings, trainings related to their specific duties and GMP trainings (Minimum one is mandatory)
- Access effectiveness of training
- Keep the records of training

GLP

- Compulsory training for contract staff recruited for activities such as cleaning and maintenance
- Continuous training/Retraining/recertification program as per policy i.e. Written test, supervised laboratory training
- Specific training for the persons working in the areas where contamination is a hazard

GLP

- Documentation: General –
- Suitable controls to ensure accuracy, integrity, availability and legibility of documents
- Appropriate control over electronic documents such as templates, forms and master documents
- Integrity of the record through out the retention period
- Appropriate control over paper documents

GLP

- Relationship between paper and electronic documents when document exists in hybrid form
- Designed, prepared, reviewed and distributed with care (distributed generally by QA)
- A proper system of revision

GLP

DOCUMENTATION

Good documentation practices

- Handwritten entries in clear, legible and indelible way
- Make and complete records at the time of each action taken
- Sign and date for any alteration made to the documents
- Original documents must be readable in case of alternation
- Provide the reason for alteration when appropriate

GLP

DOCUMENTATION

Handling of electronic data

- If documentation is handled by the electronic data processing methods, only authorized persons to enter the data in the computer
- Access to be restricted by password or any other means
- Record the changes made in the electronic data in the change control
- Protect electronically stored documents by back up transfer on DVD or suitable means

GLP

Out of specifications

- Definitions :A test value that falls outside the established specification or acceptance criteria
- Have own SOP as the guidance document "Investigating OOS test results for pharmaceutical production" by US FDA, October 2006
- Investigation as per SOP and if assignable cause CAPA to be planned
- Keep data ready for the audit like No. of OOS , laboratory error or mfg error, CAPA etc.

GLP

- A General Checklist for GLP Implementation
- Good house-keeping,
- Quality Manual/Documentation,
- Quality Policy,
- Method Validation,
- Instrumental Validation,
- System Suitability Tests,
- Calibration of Equipments/Instruments/ Calibration Schedules/Traceability,

GLP

- Equipment Log Books,
- Standard Analytical Reference Samples and their Traceability(All related Certificates/Documentation),
- Archives for Samples and Documents, (11) Specifications for the products investigated,
- Good Vendor Development,
- Study Director for Projects,
- Statistical Evaluations,

GLP

- Staff proficiency, Health and Safety,
- Procedures for Receiving, Dealing and Disposing Samples,
- Environmental monitoring in working areas,
- Effluent Treatment Monitoring and Control,
- Participation in Proficiency Testing Programs,
- Internal Audits/Checklists,
- Management Review Meetings,
- Official Audits/Surveillance Audits,
- Customer Complaints—Procedures to deal with them and Finding Solutions,

GLP

- Validation of Computer Systems and Software's,
- Continuous Performance Assessment of QA Group.
- Raw Data Collection/Traceability of Data
- Continuous up gradation of knowledge of all Personnel through Systematic Training Programs.
- Material Safety Data Sheets—Toxicity Information's, Antidotes for all Dangerous/Hazardous Chemicals.

GLP

- Continuous upgradation of knowledge of all Personnel through Systematic Training Programs.
- Material Safety Data Sheets –Toxicity Informations, Antidotes for all Dangerous/Hazardous Chemicals.
- Standard Operating Procedures,
- Sampling Procedures

GLP

- Important :

A set of highly qualified, experienced, dedicated and motivated persons to carry out the GLP program. Even if all the other conditions are satisfied, the GLP program will meet with failure, if adequate and competent Human Resources are not available.

GLP

- Summary :

Working to the best of your ability taking nothing for granted & being prepared always to justify your conclusions by following the correct procedures and criteria.

GLP

- GLP is a concept encompassing a series of principles, procedures and records in order to achieve and maintain the highest standards of quality.
- The disciplines require that you are scrupulously honest in reporting procedures, accurate at all times and diligent in attending to every detail.

GLP

- Conclusion:

In conclusion one must realize that in the pharmaceutical industry there is no margin for error and one must follow good practices in the laboratory to generate accurate, precise and reliable results.

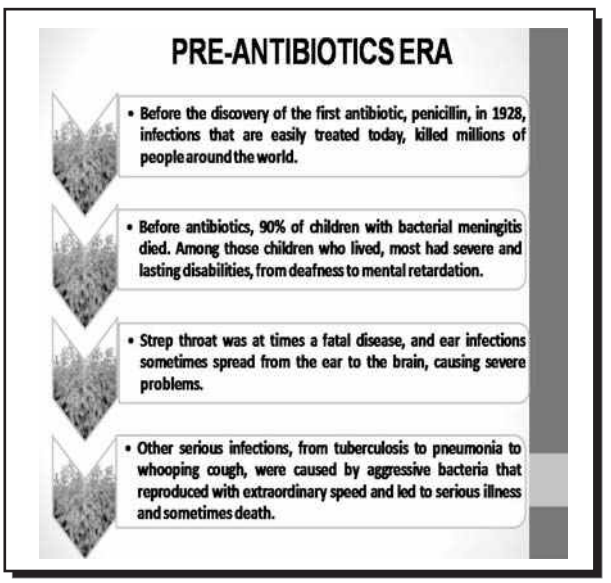
RESPONSIBLE USE OF ANTIBIOTICS SAVES LIVES

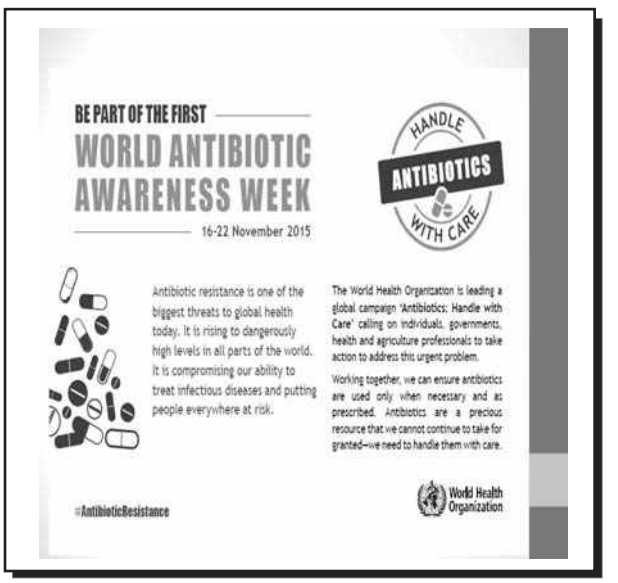
by

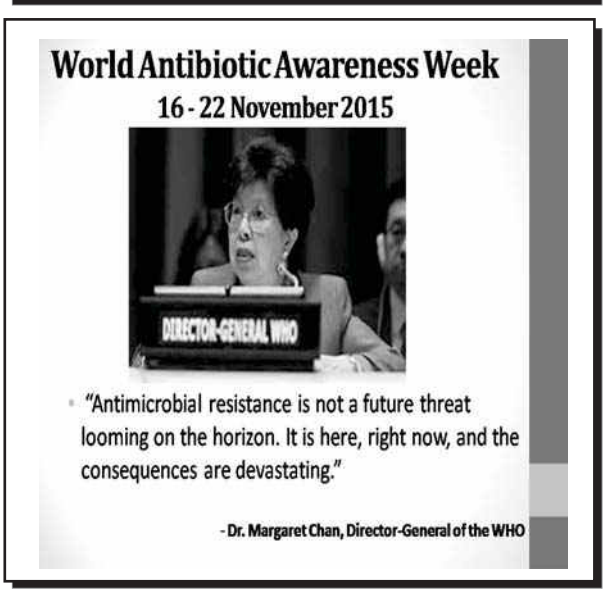
Dr. S. Sriram,

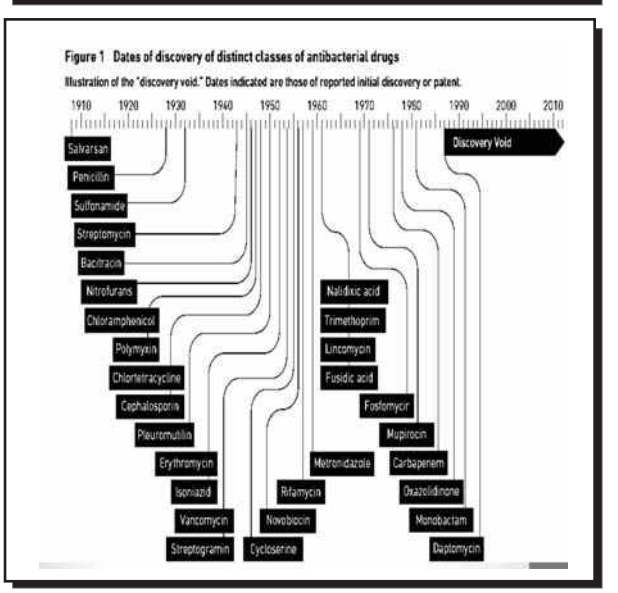
Prof & Head, Department of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore

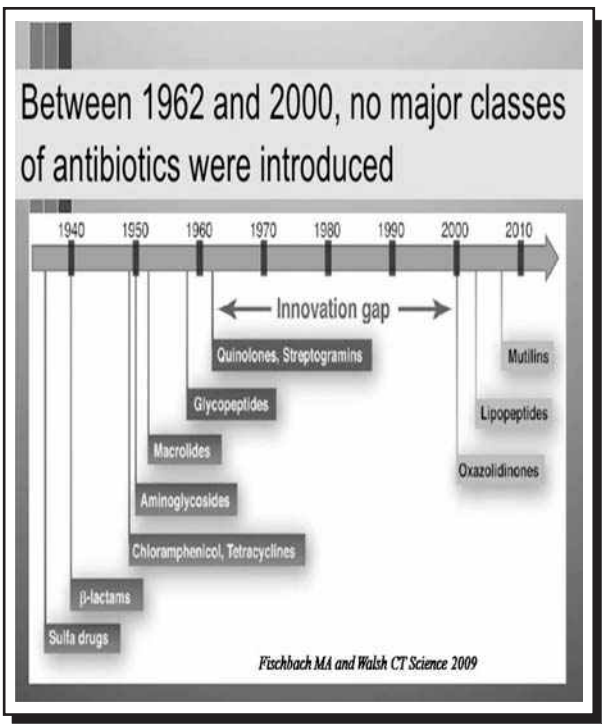
Lecture Delivered on 23rd November 2015, during the
54th National Pharmacy Week Celebration at Chennai, conducted by IPA, TN Branch)

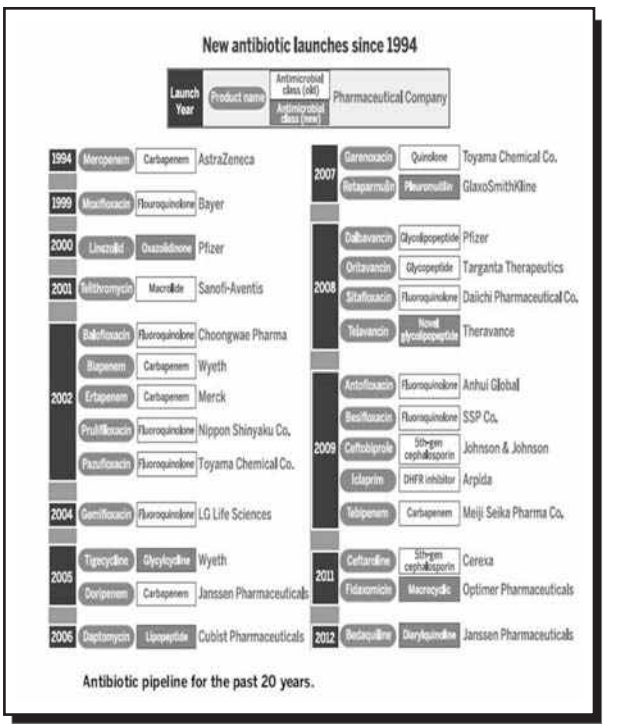


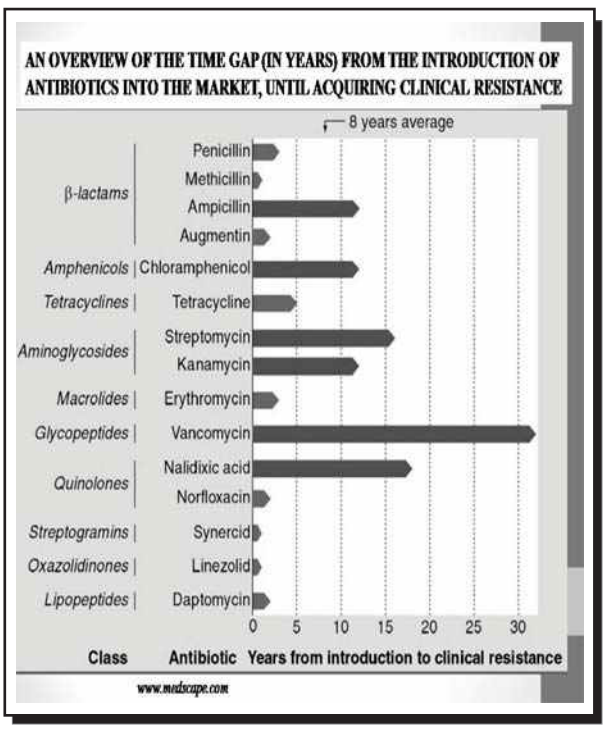


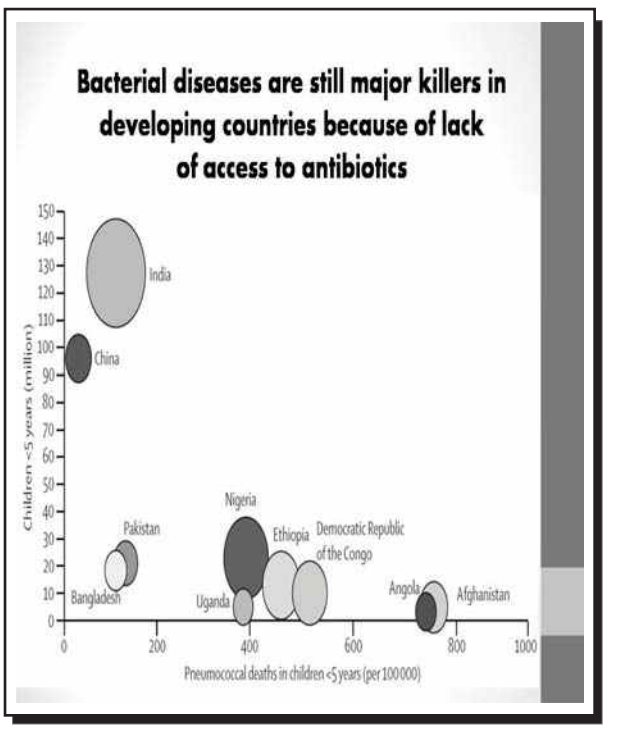


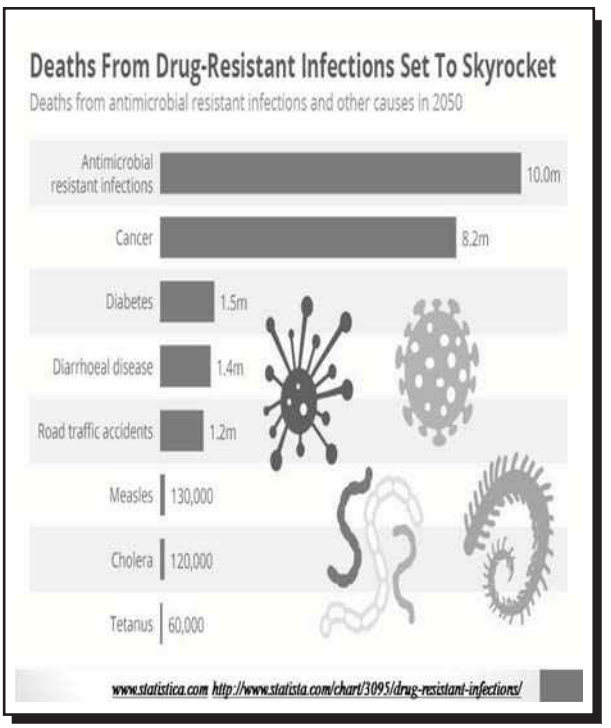


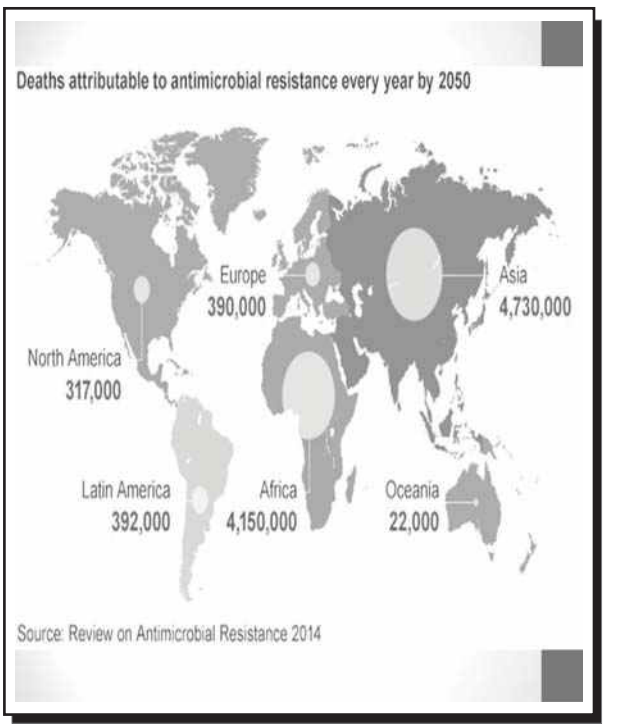

Between 1962 and 2000, no major classes of antibiotics were introduced
1940
1950
1960
1970
1980
1990
2000
2010
Innovation gap
Quinolones, Streptogramins
Glycopeptides
Macrolides
Aminoglycosides
Chloramphenicol, Tetracyclines
β-lactams
Sulfa drugs
Mutilins
Lipopeptides
Oxazolidinones
Fischbach MA and Walsh CT Science 2009

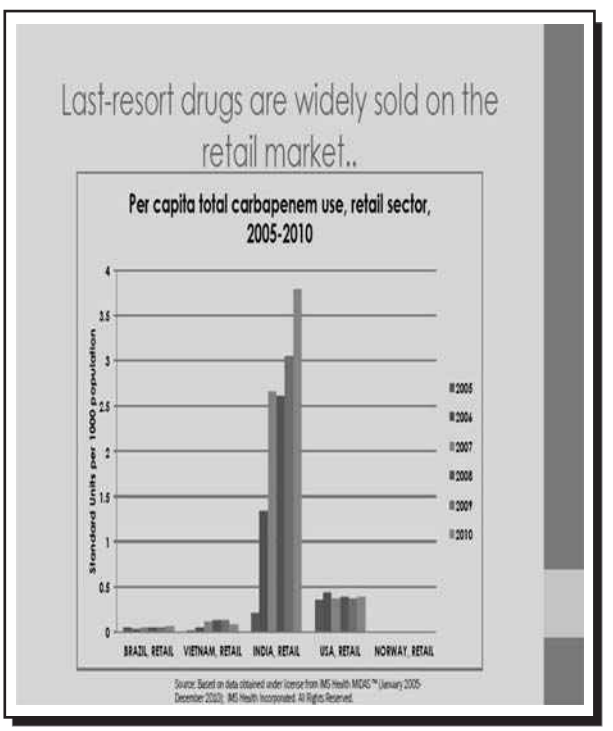

New antibiotic launches since 1994
Launch Year
Product name
Antimicrobial class (old)
Antimicrobial class (new)
Pharmaceutical Company
1994 Meropenem Carbapenem AstraZeneca
1999 Moxifloxacin Fluoroquinolone Bayer
2000 Linezolid Oxazolidinone Pfizer
2001 Telithromycin Macrolide Sanofi-Aventis
2002 Gemifloxacin Fluoroquinolone Choongwae Pharma
Biapenem Carbapenem Wyeth
Ertapenem Carbapenem Merck
Prulifloxacin Fluoroquinolone Nippon Shinyaku Co.
Pazufloxacin Fluoroquinolone Toyama Chemical Co.
2004 Garenoxacin Fluoroquinolone LG Life Sciences
2005 Tigecycline Glycylcycline Wyeth
Doripenem Carbapenem Janssen Pharmaceuticals
2006 Daptomycin Lipopeptide Cubist Pharmaceuticals
2007 Garenoxacin Quinolone Toyama Chemical Co.
Retapamulin Pleuromutilin GlaxoSmithKline
2008 Dalbavancin Glycolipopeptide Pfizer
Oritavancin Glycopeptide Targanta Therapeutics
Sitafloxacin Fluoroquinolone Daiichi Pharmaceutical Co.
Telavancin Novel glycolipopeptide Theravance
2009 Antofloxacin Fluoroquinolone Anhui Global
Besifloxacin Fluoroquinolone SSP Co.
Ceftobiprole 5th-gen cephalosporin Johnson & Johnson
Iclaprim DHFR inhibitor Arpida
Tebipenem Carbapenem Meiji Seika Pharma Co.
2011 Ceftaroline 5th-gen cephalosporin Cerexa
Fidaxomicin Macrocyclic Optimer Pharmaceuticals
2012 Bedaquiline Diarylquinoline Janssen Pharmaceuticals
Antibiotic pipeline for the past 20 years.

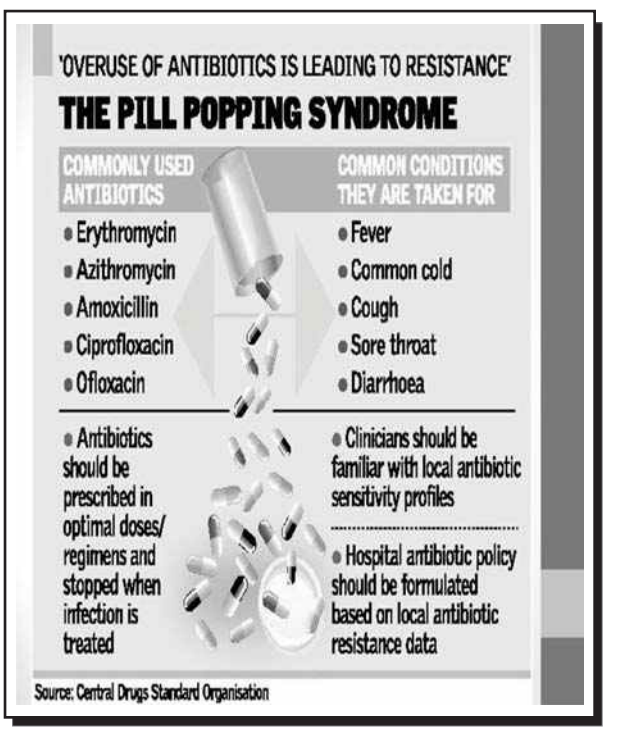

AN OVERVIEW OF THE TIME GAP (IN YEARS) FROM THE INTRODUCTION OF ANTIBIOTICS INTO THE MARKET, UNTIL ACQUIRING CLINICAL RESISTANCE
8 years average
β-lactams
Penicillin
Methicillin
Ampicillin
Augmentin
Amphenicols
Chloramphenicol
Tetracyclines
Tetracycline
Aminoglycosides
Streptomycin
Kanamycin
Macrolides
Erythromycin
Glycopeptides
Vancomycin
Quinolones
Nalidixic acid
Norfloxacin
Streptogramins
Synercid
Oxazolidinones
Linezolid
Lipopeptides
Daptomycin
0 5 10 15 20 25 30
Class
Antibiotic
Years from introduction to clinical resistance
www.medscape.com


Bacterial diseases are still major killers in developing countries because of lack of access to antibiotics
Children <5 years (million)
India
China
Nigeria
Pakistan
Ethiopia
Democratic Republic of the Congo
Bangladesh
Uganda
Angola
Afghanistan
0 200 400 600 800 1000
Pneumococcal deaths in children <5 years (per 100 000)


Deaths From Drug-Resistant Infections Set To Skyrocket
Deaths from antimicrobial resistant infections and other causes in 2050
Antimicrobial resistant infections
10.0m
Cancer
8.2m
Diabetes
1.5m
Diarrhoeal disease
1.4m
Road traffic accidents
1.2m
Measles
130,000
Cholera
120,000
Tetanus
60,000
www.statistica.com http://www.statista.com/chart/3095/drug-resistant-infections/


Deaths attributable to antimicrobial resistance every year by 2050
Europe
390,000
Asia
4,730,000
North America
317,000
Latin America
392,000
Africa
4,150,000
Oceania
22,000
Source: Review on Antimicrobial Resistance 2014


Last-resort drugs are widely sold on the retail market..
Per capita total carbapenem use, retail sector, 2005-2010
Standard Units per 1000 population
2005
2006
2007
2008
2009
2010
BRAZIL, RETAIL
VIETNAM, RETAIL
INDIA, RETAIL
USA, RETAIL
NORWAY, RETAIL


'OVERUSE OF ANTIBIOTICS IS LEADING TO RESISTANCE'
THE PILL POPPING SYNDROME
COMMONLY USED ANTIBIOTICS
Erythromycin
Azithromycin
Amoxicillin
Ciprofloxacin
Ofloxacin
COMMON CONDITIONS THEY ARE TAKEN FOR
Fever
Common cold
Cough
Sore throat
Diarrhoea
Antibiotics should be prescribed in optimal doses/ regimens and stopped when infection is treated
Clinicians should be familiar with local antibiotic sensitivity profiles
Hospital antibiotic policy should be formulated based on local antibiotic resistance data
Source: Central Drugs Standard Organisation

KILL THE BUGS NOT DRUGS

According to **WHO Report on global status of ABR and Surveillance (2014)**

WHO REPORT

- *S.aureus: resistance to beta-lactam antibiotics (MRSA)*
- *K. pneumonia: resistance to third generation Cephalosporins, and to Carbapenems.*
- *S. pneumonia: resistance or non-susceptibility to penicillin (or both)*
- *E. coli: resistance to third generation Cephalosporins and to FQ.*

58,000 neonatal sepsis deaths are attributable to drug resistant infections in India alone

(Laxminarayan et al.2013)

Methicillin-resistant Staphylococcus aureus recorded 47 percent in India

(AGAR2013; CDDEP 2015b)

In India : 13 percent of E. coli were resistant to carbapenems in 2013.

For K. pneumoniae, 57 percent were resistant in 2014 *(CDDEP 2015b)*

The new findings were published in the journal *the Lancet Infectious Diseases*. During a routine surveillance of antibiotic resistance in China, scientists discovered that a new bacterial genetic resistance mechanism called MCR-1 prevents the drug colistin from killing bacteria. (Colistin is often seen as a "last-resort" antibiotic when others aren't effective.)

The researchers found that colistin resistance was caused by a gene called MCR-1

The study was carried out by researchers from a number of institutions, including the South China Agricultural University and the China Agricultural University.

They took number of samples from animals in abattoirs, and raw meat from open markets and supermarkets in China to identify how frequently the MCR-1 gene is found in bacteria.

The study found the MCR-1 gene in E. coli collected from 15% of raw meat samples and 21% of animals tested from 2011-14. The gene was also found in E. coli from 1% of hospital inpatients in China.

WHO

WHO, countries and partners have developed a draft Global Action Plan to combat antimicrobial resistance, including antibiotic resistance, which has been submitted to the 68th World Health Assembly, took place in May 2015.

Key findings of the report include:

Very high rates of resistance have been observed in bacteria that cause common health-care associated and community-acquired infections (e.g. urinary tract infection, pneumonia)

There are significant gaps in surveillance, and a lack of standards for methodology, data sharing and coordination.

SAVE THE PILL FOR DESERVING ILL

- Sales of antibiotics and other antimicrobial medicines without prescription remain widespread, with many countries lacking standard treatment guidelines, increasing the potential for overuse of antimicrobial medicines by the public and medical professionals.
- Lack of programmes to prevent and control hospital-acquired infections remains a major problem.
- Public awareness of the issue is low in all regions, with many people still believing that antibiotics are effective against viral infections.

Do antibiotics work against all infections?

- Antibiotics do not fight infections caused by viruses, such as:
- Colds
- Flu
- Most coughs and bronchitis
- Sore throats, unless caused by strep

When are antibiotics effective?

Illness	Usual Cause		Antibiotic Needed
	Viruses	Bacteria	
Cold/Runny Nose	✓		NO
Bronchitis/Chest Cold (in otherwise healthy children and adults)	✓		NO
Whooping Cough		✓	Yes
Flu	✓		NO
Strep Throat		✓	Yes
Sore Throat (except strep)	✓		NO
Fluid in the Middle Ear (otitis media with effusion)	✓		NO
Urinary Tract Infection		✓	Yes

KEY ROLES FOR CLINICAL PHARMACISTS

- education of medical, pharmaceutical and nursing staff
- appraisal of new antimicrobials.
- formulary development
- participation in infection control
- monitoring of antibiotic consumption
- audit of local practices

EMPIRIC THERAPY

- Giving AB directly without identification and sensitivity test of bacteria, but..... *obtaining specimen for lab. analysis before giving AB.*

- Empiric therapy based on local data :
- pathogen potentially present
- susceptibility pattern
- Initiated after obtaining specimen
- Started with a combination or single Broad spectrum antibiotic.

Clinical Significance of Antibiotic Resistance

- Therapeutic failures and relapse
- Hospital goes under "antibiotic pressure"
- Need to use more costly and toxic agents
- The emergence of untreatable pathogens

Don't use antibiotics for viruses like colds or flu. Antibiotics don't work on viruses.

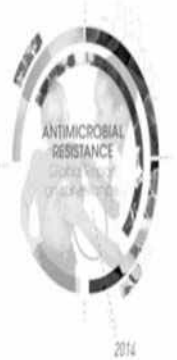
Don't pressure your doctor to give you an antibiotic.

Complete your medicine course even if you feel better.

Don't save antibiotics for later or use someone else's prescription.

One child dies every five minutes because the antibiotics given are not effective due to bacterial resistance

Zulfiqar Bhutta's presentation at ReAct conference Sep. 2010



"It is anticipated to be only a matter of time before gonococci with full resistance to the third-generation extended spectrum cephalosporins emerge and spread internationally. Consequently, gonorrhoea may become untreatable unless new drugs become available."

WHO AMR surveillance report 2014

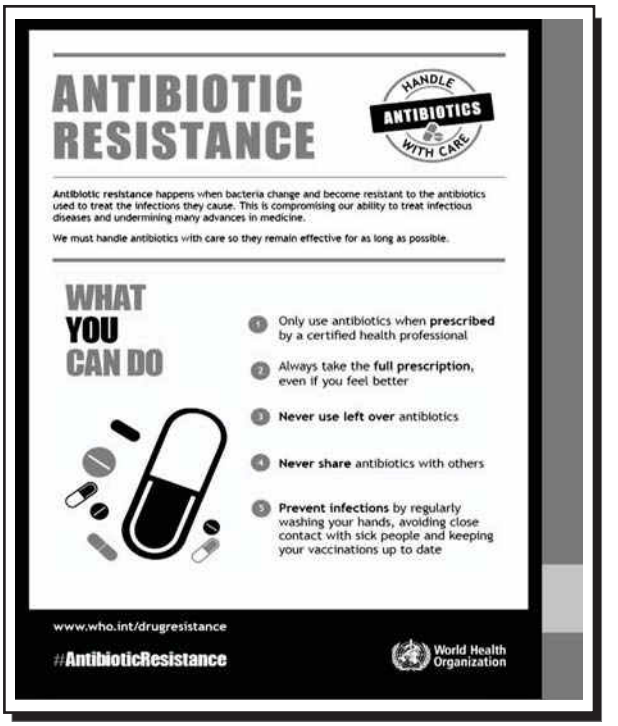
Other ways to contribute:

- Staying up to date with newer therapies
- Encouraging patients in the at risk groups to have the **seasonal influenza vaccination.**
- Promoting regular **hand hygiene.**
- Encouraging other **lifestyle choices** that help to keep the immune system healthy

Main errors in antimicrobial use in critically ill patients.

1. Choosing the antibiotic based only on the in vitro sensitivity
2. Ignoring PK/PD feature when prescribing the dose and dosage.
3. Not considering serum albumin levels when prescribing highly protein-bound antibiotics.
4. Overlooking patients with changed volume of distribution that could need dose adjustment.
5. Underestimating the creatinine clearance when prescribing the antibiotic dose during the acute phase of sepsis.
6. Over looking the high effectiveness of new replacement methods and limiting the antibiotic doses.
7. Using standard doses and regimens that may lead to sub therapeutic doses in severally ill patients.
8. Overlooking local patterns of resistance.
9. Failing to use clinical response endpoints for determining the duration of the therapy.
10. Prolonging the antimicrobial therapy unnecessarily.


ANTIBIOTIC RESISTANCE
HANDLE ANTIBIOTICS WITH CARE
Antibiotic resistance happens when bacteria change and become resistant to the antibiotics used to treat the infections they cause. This is compromising our ability to treat infectious diseases and undermining many advances in medicine.
We must handle antibiotics with care so they remain effective for as long as possible.
WHAT POLICY MAKERS CAN DO
1 Ensure you have a robust national action plan to tackle antibiotic resistance
2 Improve surveillance of antibiotic -resistant infections
3 Strengthen policies and implementation of infection prevention and control measures
4 Regulate and promote the appropriate use of quality medicines
5 Make information on the impact of antibiotic resistance available
www.who.int/drugresistance
#AntibioticResistance
World Health Organization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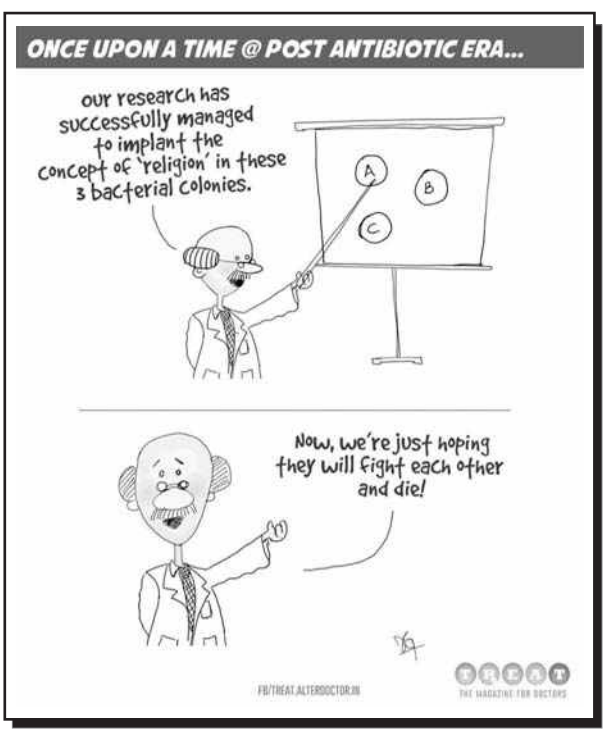
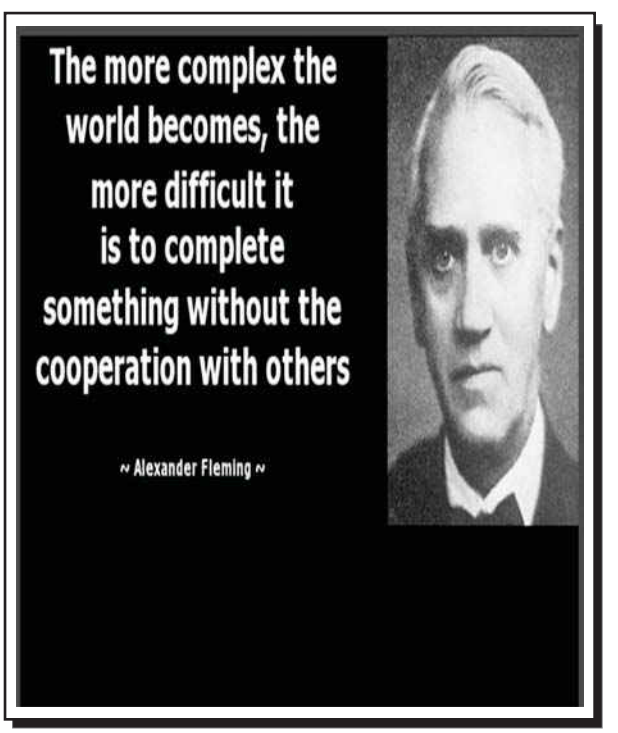
We must handle antibiotics with care so they remain effective for as long as possible.
WHAT YOU CAN DO
1 Only use antibiotics when prescribed by a certified health professional
2 Always take the full prescription, even if you feel better
3 Never use left over antibiotics
4 Never share antibiotics with others
5 Prevent infections by regularly washing your hands, avoiding close contact with sick people and keeping your vaccinations up to date
www.who.int/drugresistance
#AntibioticResistance
World Health Organization


ONCE UPON A TIME @ POST ANTIBIOTIC ERA...
our research has successfully managed to implant the concept of 'religion' in these 3 bacterial colonies.
A
B
C
Now, we're just hoping they will fight each other and die!
FB/TREAT.ALTERDOCTOR.IN
THE MAGAZINE FOR DOCTORS


The more complex the world becomes, the more difficult it is to complete something without the cooperation with others
~ Alexander Fleming ~

INFORMATION

M. PHARM & PHARM D SCHOLARHSIP 2015 – 2016

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awards scholarship to selected M. Pharm & pharm D final year students from various colleges in Tamilnadu & Puduchery 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 ot institutions outside the state of Tamilnadu for evaluation.

This was the 18th year of these awards. We received 178 applications from eight different branches – six from M Pharm and two from Pharm D, from 14 institutions. All synopses were sent to Prof Sanjay K Jain, Professorof Pharmaceutics , Dr. Hari Singh Gour Central University, Sagar, M.P & his team for evaluation. Based on their ranking, 24 students have been selected for award for scholarship as per the following details:

COLLEGE-WISE BREAK-UP

Name of the college		Awards	Received
1. J. S. S. College of Pharmacy, Ooty	:	6	37
2. Madras Medical College, Chennai	:	2	37
3. SRIPMS, Coimbatore	:	6	26
4. P. S. G. College of Pharmacy, Coimbatore	:	*	15
5. Sri Ramachandra College of Pharmacy, Chennai	:	2	10
6. SRM College of Pharmacy, Chennai	:	4	16
7. Adiparashakthi College of Pharmacy, Melmaruvathur	:	1	4
8. Mother Theresa Postgraduate Research Inst, Puducherry	:	2	7
9. School of Ph. Sciences, Vels University, Chennai	:	*	3
10. Madurai Medical College, Madurai	:	1	13
11. JKK Nataraja College of Pharmacy, Komarapalayam	:	*	1
12. Periyar College for Phar Sciences, Trichy	:	*	4
13. R V S College of Pharmaceutical Sciences, Sulur	:		3
14. Vinayaka Mission's College of Pharmacy, Salem	:		2
TOTAL	**:**	**24**	**178**

RESULT

PHARMACEUTICS

Rank	Name	Institution	Amount (Rs.)
First	Ms.V.P.Shilpa	SRIPMS, Coimbatore	12,000/-
Second	Mr.Sanjay	SRM College of Pharmacy, Kattangulathur	10,000/-
Third	Mr. Deepak Upadhyay	JSS College of Pharmacy, Ooty	8,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institution	Amount (Rs.)
First	Ms. R. Kalaiselvi	College of Pharmacy, MMC, Chennai	12,000/-
Second	Ms. Niladri Saha	JSS College of Pharmacy, Ooty	10,000/-
Third	Ms. S. Mala	College of Pharmacy, MMC, Chennai	8,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institution	Amount (Rs.)
First	Ms. K. Arthi	SRIPMS, Coimbatore	12,000/-
Second	Mr. E. Balapriyan	Adhiparasakthi College of Ph, Melmaruvathur	10,000/-
Third	Mr. Shaik Nowshad	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOLGOY

Rank	Name	Institution	Amount (Rs.)
First	Mr. Raj Kumar Pradhan	JSS College of Pharmacy, Ooty	12,000/-
Second	Mr. R. V. Venkataramanan	SRM College of Pharmacy, Kattangulathur	10,000/-
Third	Mr. V. Rajendran	SRIPMS, Coimbatore	8,000/-

PHARMACOGNOSY

Rank	Name	Institution	Amount (Rs.)
First	Mr. M. Asuvathaman	Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	12,000/-
Second	Ms. T. VelvizhiThilagam		10,000/-
Third	Ms. T. UmaPoorani	Madurai Medical College, Madurai	8,000/-

PHARMACY PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Ms. A. Sravanthi	SRM College of Pharmacy, Kattangulathur	12,000/-
Second	Ms. Deepthi Merin Raju	JSS College of Pharmacy, Ooty	10,000/-
Third	Mr. Alfatih Khalil	SRIPMS, Coimbatore	8,000/-

PHARM D – PHARMACY PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Ms. Ria Rose Roy, Ms. SubithaBabu, Ms. Shilpa Cyril, Mr. Mohammad Kamal	JSS College of Pharmacy, Ooty	15,000/-
Second	Mr. R. Aswin, Ms. Benzy Susan Joseph, Ms. Dona Maria Jetto, Ms. Elisabeth Saji Cherian	SRIPMS, Coimbatore	12,000/-

PHARM D – CLINICAL PHARMACY

Rank	Name	Institution	Amount (Rs.)
First	Ms. DesuSwathi, Ms. Kshitiji Sharma, Ms. Pornaki Rama Lakshmi, Ms. Reeba Elizabeth Royce	SRM College of Pharmacy, Kattangulathur	15,000/-
Second	Ms. K.Dhanalakshmi, Ms.Dhanuja Bhowmick, Ms. A.Divya, Ms. R. K. Divyasree	Sri Ramachandra University, Chennai	12,000/-
Third	Ms. Gangula Jaswanthi, Ms. K. Manobala, Mr. R. Nandha Kumar, Ms. S. Neha	Sri Ramachandra University, Chennai	10,000/-
Consolation	Ms. Esther K Thomas, Ms. Gayathiri G. R., Ms. Georgeena George, Ms. Ginsy Thankachan	SRIPMS, Coimbatore	10,000/-

UNIVERSITY MERIT AWARD

Our Trust decided to honor meritorious B. Pharm students by giving cash awards for those who successfully completed the course under "The Tamil Nadu Dr. MGR Medical University", every year. The awards will be given to the first three top ranking students from among the pharmacy colleges under The Tamilndau Dr. MGR Medical University. These awards are sponsored by M/s. Fourrts (India) Labs Pvt Ltd. Chennai.

This year the Dean of Studies, The Tamilnadu Dr. MGR Medical University forwarded the following names of the students who secured first three ranks.

Rank	Name	Institution	Amount (Rs.)
I	Rani. N	Jaya College of Pharmaceutical Sciences, Chennai	7,500/-
I	Afsan Fathima C. A.	Aadhi Bhagavan College of Pharmaceutical Sciences	7,500/-
II	Sadhish. I. V.	Jaya College of Pharmaceutical Sciences, Chennai	6,000/-
III	Kanimozhi. T.	K. K. College of Pharmacy, Chennai	4,000/-

ESSAY COMPETITION 2015 – FOR FINAL YEAR B. PHARM STUDENTS

Tamilnadu Pharmaceutical Sciences Welfare Trust, conducted 5th consecutive Essay Competition for the Final year B. Pharm students in Tamilnadu and Puduchery, on the subject of **"Pharmacist role – Safety First with Medicines". These awards are instituted in memory of Late. Shri. G. Swaminathan, M/s. Pharm Products Pvt Ltd. Thanjavur.**

We received totally 41 applications from 10 Colleges and they were evaluated by eminent pharmacy professionals. Based on their best marks, 3 students have been selected for awards as per the following details:

RESULT

Rank	Name	Institution	Amount (Rs.)
I	Mr. M. Vigneshwar	Jaya College of Pharmacy, Thiruninravur	10,000/-
II	Mr. T. Senthamil Selvan	J K K Nattraja College, Komarapalayam	7,500/-
II	Ms. Monisha Harini	Periyar College of Pharmaceutical Sciences, Tiruchirapalli	7,500/-

COLLEGE-WISE BREAK-UP

Name of the college		Received	Awards
1. Annamalai University, Chidambaram	:	2	
2. Sri Ramakrishna Inst of Para Medical Sciences, CBE	:	2	
3. RVS College of Pharmaceutical Sciences, Sulur	:	7	
4. Arulmigu Kalasalingam College of Pharmacy, Krishnakoil	:	4	
5. J K K Nattaraja College of Pharmacy, Namakkal	:	2	1
6. Padmavathi College of Pharmacy, Dharmapuri	:	3	
7. Jaya College of Pharmacy, Thirunindravur	:	15	1
8. Adhi Parasakthi College of Pharmacy, Melmaruvathur	:	2	
9. Sri Ramachandra University, Chennai	:	1	
10. Periyar College of Pharmaceutical Sciences, Trichy	:	3	1
TOTAL	**:**	**41**	**3**

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.

EVENTS

54th NATIONAL PHARMACY WEEK CELEBRATION, IPA – TN BRANCH

54th National Pharmacy Week Celebration was celebrated by Indian Pharmaceutical Association, Tamilnadu Branch on 23rd November 2015 at 6.30 PM in Hotel Savera, Chennai. The function started little late due to heavy rain. The function was sponsored by Tamilnadu Pharmaceutical Sciences Welfare Trust and Tamilnadu Indian Pharmaceutical Association Trust (TANIPA). Shri S. V. Veerramnai, Chief guest of the function could not attend the meeting due to heavy down pour of rain. The guests of honors were Dr. K. Chinnaswamy, President Tamilnadu Pharmacy Council and Dr. S. Manivannan, Deputy Drugs Controller of (India), CDSCO, South Zone. Mr. J. Jayaseelan, Secretary, IPA, TN Branch welcomed the gathering. Dr. S. Sriram, Professor, Head of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore, addressed the gathering on the theme **"Responsible Use of Antibiotics Saves Lives".** He stressed upon the need of use of antibiotics in a rational way in order to prevent occurrence of resistance. His address on the theme is reproduced as an article in this issue of Pharma Web. Dr. S. Manivannan, spoke about the notifications issued by government of India to restrict sale of antibiotics in the market.. **Dr. T. K. Ravi,** Principal, College of Pharmacy, SRIPMS, Coimbatore, was awarded as Pharmacist of the year sponsored by M/s. Lalchand Bhimraj, Chennai.

Tamilnadu Pharmaceutical Sciences Welfare Trust, has instituted various awards to the pharmacy graduates and the same were distributed during this function. The awards such as "M. Pharm / Pharm D Scholarship", "B. Pharm Essay Competition" (G. Swaminathan memorial award) and University Merit award to B. Pharm students sponsored by M/s. Fourrts (India) Pvt Ltd., Chennai.

The function concluded with vote of thanks by Mr. T. Sathish, Joint Secretary, IPA, TN Branch

New Books

The following New Books are available in our library for reference

1. British Pharmacopeia 2016

2. IP addendum 2016

54th National Pharmacy Week Celebration, IPA – TN Branch

54th National Pharmacy Week Celebration, Inauguration

Audience of NPW Celebration

Pharmacist of the year to Dr. T. K. Ravi

Prize distribution to the Pharmacy students

Prize distribution to the Pharmacy students

Prize distribution to the Pharmacy students

Pharma Knowledge Training Institute (Finishing School)
3rd Training Programme

Inauguration of the 3rd Training Programme by our Trust

Lecture by Mr. Sathish H Josihi, Pharma Consultant, Chennai

Students of the Training Programme

Lecture by Mr. S. Jayakumar, M/s. Apex Labs P Ltd

Students of the Training Programme

Felicitation to Mr. Sanjay Kumar Dasmohapatra, M/s. Medopharm

Lecture by Mr. K. Saravana Kumar, M/s. Fourrts India Labs P Ltd.

Soft Skill programme (Faculties & Students)

Valedictory function of the Training Programme

Certificate Distribution to the Trainees

INDUSTRIAL ORIENTATION TRAINING
on
QUALITY MANAGEMENT PERSONNEL

The 3rd training programme for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held from 18th September 2015 to 16th October 2015. As number of trainees exceeded more than 60, the training programme was conducted at The Checkers Hotel, Saidapet. Mr. R. Narayanaswamy, Mr. K. Prafulla Chandra, Mrs. Pratima Mathur, Dr. G. Selvaraj & Dr. N. Deatu, coordinators conducted this programme.

Trainees participated from the following institutions.

1 Vels University, Chennai - 42 + 2(B. Pharm Final Year students + M. Pharm Final Year students)

2 PSG College of Pharmacy, Coimbatore - 4 (B. Pharm graduates)

3 Madras Medical College, Chennai - 3 (B. Pharm graduates)

4 Madurai Medical College, Madurai - 6 (B. Pharm graduates)

5 C. L. Baid Metha College of Pharmacy, Chennai - 2 (B.Pharm graduates)

6 Ultra College of Pharmacy, Madurai - 1 (B. Pharm graduate)

Theoretical Training Programme (18th September 2015 to 30th September 2015)

- **Overview of Pharmaceutical Industry –** Mr. J. Jayaseelan, MD, M/s Delvin Formulations Pvt Ltd.
- **Schedule M Pertaining to QC functions –** Mr. M. Bhaskaran, Director of Drugs Control (Red), Tamilnadu
- **Regulatory Requirements of QC under Drugs & Cosmetics Act and Rules.**
- **Role of Govt. Drug Testing Laboratories** - Dr. G. Selvaraj, Director of Drugs Control(Retd), Tamilnadu
- **Approval of Drug Testing Laboratory** - Mr. A. Arunachalam, Deputy Director of Drugs Control (Retd), TN
- **Good Laboratory Practice - Schedule L1**
- **Reference/Retention samples storage** - Mr. Satish H Joshi, SHJ Consulting Services
- **What are the Various Divisions of a Quality Control Lab, Explanation of Different Equipments Used in Q.C. Lab**
- **Quality essential in Pharmaceutical industry - Quality Control and its Relationship with Quality Assurance, Production, R&D, and Regulatory Divisions**

of Pharma Industry - Mr. P. R. Abdul Hameed, Executive Director- Technical, M/s. Medopharm

- **General notice in Pharmacopeia**
- **General requirements for Tablets, Capsule, Oral liquids & external preparations –** Mr. S. Murali, M/s. Apex Laboratories P Ltd, Chennai
- **Basic Calculations in Quality Control, Dilutions and Statistical Analysis**
- **Qualitative Analysis, Quantitative Analysis & Elemental Analysis** - Mr. S. Vikraman, M/s. Apex Laboratories P Ltd, Chennai
- **Documentation and records in QC**
- **Sampling of Raw Materials, In- process Materials and Finished products –** Mr. K. Saravanakumar, M/s. Fourrts (india) Laboratories P Ltd, Chennai
- **Pharmaceutical formulation development Role of QC** - Dr. D. Natarajan, Pharma Consultant
- **What is Pharmacopeia, Pharmacopoeias of Different Countries, How to use pharmacopoeia, Monographs and their explanation** - Dr. N. Murugesan, Director, CDTL, Chennai
- **Air Systems, Water Systems, Their sampling & Testing**
- **Qualification of laboratory equipments** - Mr. S. Jayakumar, M/s. Apex Laboratories P Ltd, Chennai
- **Reference Standards and Working Standards**
- **Dissolution & its Importance, Methods used in Dissolution Testing** - Mr. K. M. Sridhar, M/s. Fourrts (india) Laboratories P Ltd, Chennai
- **Equipments used in QC laboratory**
- **Calibration of QC equipments - Part 1 & Pat 2** - Dr. R. Venkidesh, Sai Mirrah Innopharm, Pvt. Ltd., Chennai
- **Introduction to Theory of Chromatography –** Dr. V. Manohar, Director, Indian Institute of Chromatography & Mass Spectrometry, Chennai
- **High Performance Liquid Chromatography(HPLC) – Instrumentation & Columns** Mr. P. Raman, IICMS
- **Detectors in HPLC –** Ms. U. Rampriya, IICMS
- **Gas Chromatography(GC) – Instrumentation & Applications**
- **Method Development & A case study analysis** - Mr. S. Saravanan, IICMS
- **Introduction to Mass Spectrometry and application –** Mr. K. Mohan, IICMS
- **Analytical method validation**
- **ICH Guidelines - An introduction** - Mr. G. T. Arularasu, M/s. Fourrts India Laboratories P Ltd, Chennai

- **Microbiology - An introduction**
- **Microbiology for non-sterile preparations** - Mr. Mujibur Rahman, M/s. Fourrts India Laboratories P Ltd, Chennai
- **Quality Risk Management –** Mr. Narendira Kumar, Head - Quality Assurance, M/s. Orchid Healthcare
- **Stability Testing, Accelerated and Real Time**
- **Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability** - Mr. M. Ramalingam, M/s. Fourrts India Laboratories India P Ltd, Chennai
- **Out of specification / Out of trend handling**
- **Safe handling of chemicals and reagents**
- **Quality Assurance - Basic concepts and its relevance. Roles and responsibilities**
- **ICH Guidelines, MHRA, USFDA guideline on QC. Change control, handling of deviation, market complaints and CAPA** - Mr. Sanjay Kumar Das Mohapatra, President, Technical & Operation, M/s. Medopharm
- **Soft Skills Program (Full Day) –** Mr. Senthil Kumar and his Associates

Practical Training (5th October to 15th October 2015)

The practical training on Quality Control and Quality Assurance in the industries was held from 5th October 2015 to 15th October 2015. Sai Mirra Innopharm Pvt. Ltd., Tablets (India) Pvt. Ltd., Apex Laboratories Pvt. Ltd., Fourrts India Laboratories Pvt. Ltd., Medopharm, The Madras Pharmaceuticals, Orchid Pharmaceuticals, Bafna Pharmaceuticals & Central Drug Testing Laboratories, Chennai, offered their facilities for training the participants. The candidates were sent for training in a group of 4 - 5. During the industrial training, they were assessed on common parameters by the Heads of Quality department of the respective industries.

The final written evaluation was held on 16th October 2015. On that day all the participants were awarded course completion certificates. Shri. M. Sardarmal Chordia, MD of M/s. Medopharm was the Chief Guest of the function and Dr. M. Ramanathan, Principal, PSG College of Pharmacy was the Guest of Honor. Following this, placement interviews were conducted. Technical and HR Department personnel from Sai Mirra Innopharm Pvt. Ltd., Apex Laboratories Pvt. Ltd., Fourrts (India) Laboratories Pvt Ltd & MMC Health Care Ltd. The trainees who completed final year B.Pharm were selected by the above said companies as trainee chemists.

The feedback about the programme was obtained from the Pharmacy colleges as well as Pharma Industries. They appreciated that such a programme needs to be conducted often in order to improve the knowledge of Pharmacy students.

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th October, 2015

G.S.R. 826(E).— Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare vide number G.S.R. 69(E), dated the 3rd February, 2015, as required by Section 12 read with Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), 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 12th February, 2015;

And, whereas, no objections or suggestions were received from the public on the said rules;

Now, therefore, in exercise of the powers conferred by 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 (Seventh Amendment) Rules, 2015.
   (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 122 DA, in sub-rule (3), for the Explanation, the following Explanation shall be substituted, namely:—

   'Explanation.— For the purposes of these rules,—

   (a) "Clinical Trial" means a systematic study of any new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic), and/or adverse effects with the objective of determining safety and/or efficacy of the new drug;

   (b) "Global Clinical Trial" means any clinical trial which is conducted as part of multi-national clinical development of a drug;

   (c) "Investigational New Drug" means a new chemical entity or a product having therapeutic indication but which has never been tested earlier on human being;

   (d) "New Chemical Entity" means an active substances in developmental stage which may be specified as a drug under the Act, after undergoing any clinical trial.'.

3. In the said rules, rule 122 DAA shall be omitted.
4. In the said rules, in Schedule A, in Form 44, under the heading "A. Permission to market a new drug:", after item (10), the following items shall be inserted at the end, namely:—

   "(11) New Chemical Entity and Global Clinical Trial-

(a) Assessment of risk versus benefit to the patients

   (b) Innovation vis-à-vis existing therapeutic option

   (c) Unmet medical need in the country."

5. In the said rules, in *Schedule*, in APPENDIX I, after sub-item 11.1, the following shall be inserted, namely:-

   "12. New Chemical Entity and Global Clinical Trial:

   12.1 Assessment of risk versus benefit to the patients

   12.2 Innovation vis-à-vis existing therapeutic option

   12.3 Unmet medical need in the country."

[F. No. X.11014/4/2014-DFQC]

K. L. SHARMA, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated the 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number GSR 558(E), dated the 17th July, 2015.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health And Family Welfare)

NOTIFICATION

New Delhi, the 29th December, 2015

G.S.R.1011(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), 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;

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 Under Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011;

The Central Government is of the opinion that circumstances have arisen which render it necessary to make the rules without consulting the Drugs Technical Advisory Board and as per provisos to sub-section (1) of section 12 and sub-section (1) of section 33, the Central Government purposes to consult the Drugs Technical Advisory Board within six months from the date of final publication of these rules.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (8th Amendment) Rules, 2015.

(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 said rules), in rule 24,-

(a) in sub-rule (1),

(i) for the words “one thousand rupees”, the words “ten thousand rupees” shall be substituted;

(ii) in the proviso, for the words “one hundred rupees”, the words “one thousand rupees” shall be substituted;

(b) in sub-rule (3), for the words “two hundred and fifty rupees shall be paid”, the words “one thousand five hundred rupees shall be paid for making amendment in the licence or” shall be substituted.

3. In the said rules, in rule 24-A,-

(a) in sub-rule (3),

(i) in clause (i), for the words and letters “one thousand and five hundred US dollars”, the words and letters “ten thousand US dollars” shall be substituted;

(ii) in clause (ii), for the words and letters “one thousand US dollars” wherever they occur, the words and letters “five thousand US dollars” shall be substituted;

(b) in sub-rule (5), for the words and letters “five thousand US dollars”, the words and letters “twenty five thousand US dollars” shall be substituted;

(c) in sub-rule (7), for the words and letters “three hundred US dollars or its equivalent in Indian rupees shall be paid”, the words and letters “one thousand eight hundred US dollars or its equivalent in Indian rupees shall be paid for making amendment in the registration certificate or” shall be substituted.

4. In the said rules, in rule 34, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “five thousand rupees for a single drug and an additional fee of two thousand rupees” shall be substituted.

5. In the said rules, in rule 34A, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “six hundred rupees for a single drug and an additional fee of three hundred rupees” shall be substituted.

6. In the said rules, in rule 59,-

(a) in sub-rule (2),-

(i) for the words and letters "a fee of rupees one thousand and five hundred or in Form 19A accompanied by a fee of rupees five hundred, as the case may be, or in the case of drugs included in Schedule X shall be made in Form 19C accompanied by a fee of rupees five hundred", the words and letters "a fee of fifteen thousand rupees or in Form 19A accompanied by a fee of five thousand rupees, as the case may be, or in the case of drugs included in Schedule X shall be made in Form 19C accompanied by a fee of five thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees ten", the words "five hundred rupees" shall be substituted;

(b) in sub-rule (3),-

(i) for the words "rupees one hundred and fifty", the words "one thousand and five hundred rupees" shall be substituted;

(ii) in the proviso, for the words "rupees two", the words "two hundred rupees" shall be substituted;

(c) for sub-rule (4), the following sub-rule shall be substituted, namely:-

"(4) Application for renewal of a licence to sell, stock, exhibit or offer for sale or distribute drugs, after its expiry but within six months of such expiry shall be accompanied by a fee of fifteen thousand rupees plus an additional fee at the rate of five thousand rupees per month or part thereof in Form 19, five thousand rupees plus an additional fee at the rate of two thousand five hundred rupees per month or part thereof in Form 19A and five thousand rupees plus an additional fee at the rate of two thousand five hundred rupees per month or part thereof in Form 19C:

Provided that in the case of an itinerant vendor or an applicant desiring to open a shop in a village or town having a population of five thousand or less the application for such renewal shall be accompanied by a fee of five hundred rupees plus an additional fee at the rate of four hundred rupees per month or part thereof.".

7. In the said rules, in rule 62-C,-

(a) in sub-rule (1),-

(i) for the words "rupees five hundred", the words "five thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty", the words "five thousand rupees plus an additional fee at the rate of one thousand rupees" shall be substituted;

(b) in sub-rule (2), for the words "rupees one hundred and fifty", the words "one thousand and five hundred rupees" shall be substituted.

8. In the said rules, in rule 67A,-

(a) in sub-rule (2),-

(i) for the words "rupees two hundred and fifty", the words "two thousand five hundred rupees" shall be substituted;

(ii) in the proviso, for the words "rupees two hundred and fifty plus an additional fee at the rate of rupees fifty", the words "two thousand five hundred rupees plus an additional fee at the rate of five hundred rupees" shall be substituted;

(b) in sub-rule (3), for the words "rupees fifty", the words "five hundred rupees" shall be substituted.

9. In the said rules, in rule 69,-

(a) in sub-rule (2),-

(i) in clause (a), for the words "rupees five hundred plus an inspection fee of rupees two hundred", the words "five thousand rupees plus an inspection fee of two thousand rupees" shall be substituted;

(ii) in clause (b), for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(iii) in clause (c), for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(b) in sub-rule (3),-

(A) in clause (i), for the words "rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof in addition to an inspection fee of rupees two hundred", the words "five thousand rupees plus an additional fee at the rate of one thousand rupees per month or part thereof in addition to an inspection fee of two thousand rupees" shall be substituted;

(B) in clause (ii), for the words "rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand", the words "fifty thousand rupees plus an additional fee at the rate of ten thousand rupees per month or part thereof in addition to an inspection fee of ten thousand rupees" shall be substituted;

(C) in clause (iii), for the words "rupees six thousand plus an additional fee at the rate of rupees one thousand per month or part thereof in addition to an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees plus an additional fee at the rate of ten thousand rupees per month or part thereof in addition to an inspection fee of fifteen thousand rupees" shall be substituted;

(c) in sub-rule (4), for the words "rupees one thousand", the words "five thousand rupees" shall be substituted;

(d) in sub-rule (5), for the words "rupees three hundred for each additional item of drug. Applications in Form 24B for licence to manufacture for sale and distribution for repacking for more than 10 items of each category or for manufacture of additional item of drug shall be accompanied by additional fee of rupees one hundred", the words "one thousand and five hundred rupees for each additional item of drug and applications in Form 24B for licence to manufacture for sale and distribution for repacking for more than ten items of each category or for manufacture of additional item of drug shall be accompanied by additional fee of five hundred rupees" shall be substituted.

10. In the said rules, in rule 69A,-

(a) in sub-rule (1),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred plus an additional fee at rate of rupees one thousand", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees plus an additional fee at rate of ten thousand rupees" shall be substituted;

(b) in sub-rule (3), for the words "rupees three hundred", the words "one thousand five hundred rupees" shall be substituted;

(c) in sub-rule (4), for the words "rupees one thousand", the words "five thousand rupees" shall be substituted.

11. In the said rules, in rule 75,-

(a) in sub-rule (1),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees plus an additional fee of ten thousand rupees or a part thereof in addition to the inspection fee of fifteen thousand rupees" shall be substituted;

(b) in sub-rule (2),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees plus an additional fee of ten thousand rupees or a part thereof in addition to the inspection fee of fifteen thousand rupees" shall be substituted;

(c) in sub-rule (3),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "rupees six thousand plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees plus an additional fee of ten thousand rupees or a part thereof in addition to the inspection fee of fifteen thousand rupees" shall be substituted;

(d) in sub-rule (4), for the words "rupees one thousand", the words "five thousand rupees", shall be substituted;

(e) in sub-rule (5), for the words "rupees three hundred", the words "one thousand five hundred rupees", shall be substituted.

12. In the said rules, in rule 75A,-

(a) in sub-rule (1),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "six thousand rupees and an inspection fee of rupees one thousand and five hundred plus an additional fee at the rate of rupees one thousand", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees plus an additional fee at the rate of ten thousand rupees" shall be substituted;

(b) in sub-rule (1A),-

(i) for the words "six thousand rupees and an inspection fee of one thousand and five hundred rupees", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the proviso, for the words "six thousand rupees plus an additional fee of rupees one thousand per month or a part thereof in addition to the inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees plus an additional fee of ten thousand rupees or a part thereof in addition to the inspection fee of fifteen thousand rupees" shall be substituted" shall be substituted;

(c) in sub-rule (3), for the words "rupees three hundred", the words "one thousand five hundred rupees" shall be substituted;

(d) in sub-rule (4), for the words "rupees one thousand", the words "five thousand rupees" shall be substituted.

13. In the said rules, in rule 82, for the words "rupees two hundred and fifty", the words "one thousand rupees" shall be substituted.

14. In the said rules, in rule 85B,-

(a) in sub-rule (2),-

(i) in clause (a), for the words "rupees two hundred for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of rupees one hundred for the first inspection or rupees fifty", the words "one thousand rupees for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of five hundred rupees for the first inspection or two hundred fifty rupees" shall be substituted;

(ii) in clause (b), for the words "rupees two hundred for the manufacture of Homoeopathic potentised preparations only and an inspection fee of rupees one hundred for the first inspection and rupees fifty", the words "one thousand rupees for the manufacture of Homoeopathic potentised preparations only and an inspection fee of five hundred rupees for the first inspection and two hundred fifty rupees" shall be substituted;

(iii) in clause (c), for the words "rupees two hundred for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of rupees one hundred for the first inspection or rupees fifty", the words "one thousand rupees for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of five hundred rupees for the first inspection or two hundred fifty rupees" shall be substituted;

(b) in sub-rule (3),-

(i) in clause (a), for the words "rupees two hundred plus an additional fee at the rate of rupees one hundred per month or part thereof and an inspection fee of rupees fifty", the words "one thousand rupees plus an additional fee at the rate of five hundred rupees per month or part thereof and an inspection fee of two hundred fifty rupees" shall be substituted;

(ii) in clause (b), for the words "rupees two hundred plus an additional fee at the rate of rupees one hundred per month or part thereof and an inspection fee of rupees fifty", the words "one thousand rupees plus an additional fee at the rate of five hundred rupees per month or part thereof and an inspection fee of two hundred fifty rupees" shall be substituted;

(iii) in clause (c), for the words "rupees two hundred plus an additional fee at the rate of rupees one hundred per month or part thereof and an inspection fee of rupees fifty", the words "one thousand rupees plus an additional fee at the rate of five hundred rupees per month or part thereof and an inspection fee of two hundred fifty rupees" shall be substituted;

(c) in sub-rule (4), for the words "rupees fifty", at both the places where they occur, the words "two hundred and fifty rupees" shall be substituted;

(d) in sub-rule (5), for the words "rupees fifty", the words "two hundred and fifty rupees" shall be substituted.

15. In the said rules, in rule 85ED, for the words "rupees two hundred", the words "one thousand rupees" shall be substituted.

16. In the said rules, in rule 90, in sub-rule (2) for the words "rupees two hundred and fifty", the words "two thousand five hundred rupees" shall be substituted.

17. In the said rules, in rule 122A, in sub-rule (1), in clause (b),-

(i) for the words "fifty thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted;

(ii) in the both provisos, for the words "fifteen thousand rupees", at both the places where they occur, the words "one lakh rupees" shall be substituted.

18. In the said rules, in rule 122B, in sub-rule (1), in clause (b),-

(i) for the words "fifty thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted;

(ii) in the first proviso, for the words "fifty thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted.

(iii) in the second proviso, for the words "fifteen thousand rupees", the words "one lakh rupees" shall be substituted.

19. In the said rules, in rule 122D, in sub-rule (1), for the words "fifteen thousand rupees", the words "one lakh rupees" shall be substituted.

20. In the said rules, in rule 122DA, in sub-rule (2),-

(i) in clause (a), for the words "fifty thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted;

(ii) in clause (b), for the words "twenty five thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted;

(iii) in clause (c), for the words "twenty-five thousand rupees", the words "two lakh fifty thousand rupees" shall be substituted;

21. In the said rules, in rule 122F,-

(a) in sub-rule (1),-

(i) for the words "rupees six thousand and an inspection fee of rupees one thousand and five hundred", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees" shall be substituted;

(ii) in the first proviso, for the words "rupees six thousand and inspection fee of one thousand and five hundred plus and additional fee at the rate of rupees one thousand", the words "fifty thousand rupees and an inspection fee of fifteen thousand rupees and additional fee at the rate of ten thousand rupees" shall be substituted;

(b) in sub-rule (2), for the words "rupees one thousand", the words, "five thousand rupees" shall be substituted;

(c) in sub-rule (3), for the words "rupees three hundred", the words, "one thousand five hundred rupees" shall be substituted.

22. In the said rules, in rule 122K, for the words "rupees two hundred and fifty", the words "one thousand rupees" shall be substituted.

23. In the said rules, in rule 129A,-

(a) in sub-rule (1), for the words and letters, "two hundred and fifty US dollars or its equivalent to Indian rupees for each brand of cosmetic" the words and letters "two thousand US dollars or its equivalent to Indian rupees for each brand of cosmetic and a fee of fifty US dollars for each variant" shall be substituted;

(b) in sub-rule (5), for the words and letters "one hundred US dollars", the words and letters "five hundred US dollars" shall be substituted.

24. In the said rules, in rule 138,-

(a) in sub-rule (1), for the words "rupees two thousand and five hundred and an inspection fee of rupees one thousand", the words "fifteen thousand rupees and an inspection fee of five thousand rupees" shall be substituted;

(b) in sub-rule (2), for the words "rupees two thousand and five hundred plus an additional fee at the rate of rupees four hundred per month or part thereof in addition to an inspection fee of rupees one thousand", the words "fifteen thousand rupees plus an additional fee at the rate of two thousand rupees per month or part thereof in addition to an inspection fee of five thousand rupees" shall be substituted;

(c) in sub-rule (3), for the words "rupees one hundred for each item subject to a maximum of rupees three thousand", the words "five hundred rupees for each item subject to a maximum of fifteen thousand rupees" shall be substituted;

(d) in sub-rule (4), for the words "rupees two hundred and fifty", the words "one thousand rupees" shall be substituted.

25. In the said rules, in rule 138A,-

(a) in sub-rule (1), for the words "rupees two thousand and five hundred and an inspection fee of rupees one thousand", the words "fifteen thousand rupees and an inspection fee of five thousand rupees" shall be substituted;

(b) in sub-rule (2), for the words "rupees two thousand and five hundred plus and additional fee at the rate of rupees four hundred", the words "fifteen thousand rupees plus and additional fee at the rate of one thousand and five hundred rupees" shall be substituted;

(c) in sub-rule (5), for the words "rupees one hundred for each item subject to a maximum of rupees three thousand", the words "five hundred rupees for each item subject to a maximum of fifteen thousand" shall be substituted;

(d) in sub-rule (6), for the words "rupees two hundred and fifty", the words "one thousand rupees" shall be substituted.

26. In the said rules, in rule 139AD, for the words "rupees two hundred and fifty", the words "one thousand five hundred rupees" shall be substituted.

27. In the said rules, in rule 150B,-

(a) in sub-rule (1),-

(i) for the words "rupees six thousand in the case of testing of drugs specified in Schedules C and C(1) and rupees one thousand and five hundred", the words "fifty thousand rupees in the case of testing of drugs specified in Schedules C and C(1) and fifteen thousand rupees" shall be substituted;

(ii) in the second proviso, for the words "rupees six thousand in the case of testing of drugs specified in Schedules C and C(1) and rupees one thousand and five hundred in the case of testing of drugs other than those specified in Schedule C and Schedule C(1), Homoeopathic medicines and cosmetics, plus an additional fee at the rate of rupees one thousand", the words "fifty thousand rupees in the case of testing of drugs specified in Schedules C and C(1) and fifteen thousand rupees in the case of testing of drugs other than those specified in Schedule C and Schedule C(1), Homoeopathic medicines and cosmetics, plus an additional fee at the rate of ten thousand rupees" shall be substituted.

(b) in sub-rule (2), for the words "rupees one thousand and five hundred in case of drugs specified in Schedule C and Schedule C(1) and rupees one thousand" the words "fifteen thousand in case of drugs specified in Schedule C and Schedule C(1) and ten thousand rupees" shall be substituted.

28. In the said rules, in rule 151-I, for the words "rupees two hundred and fifty" the words "one thousand five hundred rupees" shall be substituted.

[F.No. X-11014/7/2015-DFQC]
K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number GSR 918 (E) dated 30.11.2015.

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File No. DCG (I)/Misc/2015 (187)

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi
Dated: 18-11-2015

Office Order

Central Drugs Standard Control Organisation (CDSCO), DGHS, Ministry of Health and Family Welfare, Government of India has initiated the process of implementation of e-Governance with respect to licensing system under the Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder in phased manner to bring transparency, accountability and efficiency in the drug regulatory system.

An online licensing system "SUGAM" has been developed with respect to Import & Registration of drugs and Import license for personal use. In this regard, portal www.cdscoonline.gov.in has been inaugurated and rolled-out to the country by Shri. J. P. Nadda, Hon'ble Minister of Health & Family Welfare on 14.11.2015.

The said online system has now become operational for stakeholders. Now, the applicants may submit their applications with respect to above subject through the online system for review and processing by CDSCO.

All concerned officers of CDSCO are therefore hereby directed to start online processing of such applications immediately and take appropriate action as per the requirements of Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder.

(Dr. G. N. Singh)
Drugs Controller General (India)

To

1. All JDC(I)s / DDC(I)s / ADC(I)s of CDSCO (HQ)
2. All Zonal / Sub-zonal / Port offices of CDSCO
3. Director (Admin), CDSCO

Copy to:-

1. PPS to Secretary (Health) / DGHS / AS (F&D) / JS (R) / Director (Drugs)
2. All Pharmaceutical Associations
3. Guard File

NEWS

Over 40K Pharmacies Down Shutters Across Tamil Nadu

More than 40,000 pharmacies in the state of Tamil Nadu, including 5,000 in Chennai, downed shutters on Wednesday in protest against the government's decision to regularize sale of medicines online. The strike began at 6 am with hundreds of pharmacists gathering at Valluvar Kottam.

While some people, in need of medication daily, stocked up beforehand, several people were caught unawares. Long queues were seen at pharmacies at hospitals as a result. "I need daily medication as I suffer from heart ailment. I was cautioned about the strike beforehand by my pharmacist, so I managed to buy my pills two days ahead," said U Nirmala of Chintadripet. However K Rajkumar of CIT Nagar, didn't know about the strike and had to come to a private hospital 5km from his house to buy pills for his wife, who suffers from migraine.

"We had an unusually long queue at the hospital pharmacy because of the strike. While we could serve 90% of the customers, a few returned home disappointed as some of the drugs were not available," said a pharmacist at a private hospital on Greams Road.

Dubbing the strike a 'complete success', general secretary of Chennai District Chemists and Druggists Association, T Natarajan, said, "Our priority was to ensure that none of the patients Suffered due to our strike. So we met the Health secretary on Tuesday and assured him that if anyone wants emergency medication they can call us and we would supply the drugs. Also, 150 pharmacies attached to various hospitals in the city operated as usual," he said. Natarajan said the committee that took the decision on regularizing e-pharmacy did not interact with any of the traders and took an independent call. "They gave us six days' time and an email id to send in our grievances. But they paid no heed to hundreds of emails we sent them explaining the adverse effects of online sale of drugs," he added.

"The biggest danger in e-pharmacies is the unchecked sale of prescription drugs like sleeping pills, to anyone and everyone who can access the internet. Spurious drugs can also enter the market as a result of online sales and there are also the dangers associated with sale of medicines without a prescription," he said.

Source: *The Times of India, 15th October 2015*

Frequent Use of Antibiotics May Make Kids Fatter

Children who regularly use antibiotics gain weight faster than those who have never taken the drugs, according to new research that suggests childhood antibiotics may have lasting effect on body weight well into adulthood. The study, published in the International Journal of Obesity , examined the electronic medical records of 1,63,820 children aged 3 to 18, counting antibiotic prescriptions, body weight and height.

The records, which covered pediatric exams from 2001 through 2012, showed that one in five -over 30,000 children -had been prescribed antibiotics seven or more times.

By the time those children reached age 15, they weighed, on average, about 3 pounds more than children who had received no antibiotics. While earlier studies have suggested a link between antibiotics and childhood weight gain, they typically have relied on a mother's memories of her child's antibiotic use. The new research is significant because it's based on documented use of antibiotics in a child's medical record.

“Not only did antibiotics contribute to weight gain at all ages, but the contribution of antibiotics to weight gain gets stronger as you get older," said Dr Brian S Schwartz, the first author and a professor in the department of environmental health sciences at the Johns Hopkins Bloomberg School of Public Health. Scientists have known for years that antibiotic use promotes weight gain in livestock, which is why large food producers include low doses of antibiotics in the diets of their animals.

Source: *The Times of India, 23rd October 2015*

Govt. Agencies Can't Fix Max Price For Condoms, Says HC

Is condom a medicine? If so, can government agencies fix a maximum price for it under Drug Price Control Order (DPCO)? No, the Madras high court said, adopting a July 2015 order of the Delhi high court lock stock and barrel.

The first bench of Chief Justice Sanjay Kishan Kaul and Justice T S Sivagnanam allowed the petition filed by TTK Protective Devices Ltd, saying it concurred with the decision of the Delhi high court which had in July quashed the orders of National Pharmaceuticals Pricing Authority (NPPA) dated November 5, 2013 and July 10, 2014.

"NPPA exceeded the powers conferred by DPCO-2013 while fixing the ceiling price for condoms. Language of paragraph 4 [in DPCO] is unambiguous and makes clear the legislative intent that the ceiling of price can be fixed only for scheduled formulations of specified strengths and dosages. It cannot be applicable to condoms, the dosage and strength of which have not been specified," the Delhi high court said. Fixing a ceiling price for condoms is impermissible under law, it added.

Two companies, Reckitt Benckiser and J K Ansell Ltd, which promoted Durex, Kohinoor and Kamasutra brands of condoms assailed the orders of NPPA in court. Chennai-based TTK Protective Devices Limited challenged them in the Madras high court. As the Delhi high court had completed hearing and reserved its orders, the Madras high court chose to await the outcome. On July 10, 2015 the Delhi court delivered the verdict which has now been followed verbatim by the Madras high court.

It had been the stance of additional solicitor-general G Rajagopalan and senior central government panel counsel RabuManohar that condoms ought to be classified as medicines whose prices are amenable to government control. The Delhi high court also received similar submissions by the Centre, which said there could be no 'gradations' in drugs and dismissed the claims of manufacturers that the government had not taken into account the classification of 'pleasure condoms' and 'utility condoms'. Condoms are at present in the national list of essential medicines, it said.

The companies argued that price cap will have adverse impact on production, which will be detrimental to population control measures. Noting that testing methods specified in DPCO-2013 were unworkable, the companies said they make advanced version of pleasure condoms which were distinct from the basic/utility condoms. "Fixation of a common ceiling price for both the categories under the impugned orders is violative of fundamental right to equality," they said

Source: *The Times of India, 23rd October 2015*

Chemical in Sunscreen is A Coral Killer, Says Study

A common ingredient found in sunscreen is toxic to coral and contributing to the decline of reefs around the world, according to new research published on Tuesday.

Oxybenzone, a UV-filtering chemical compound found in 3,500 brands of sunscreen worldwide, can be fatal to baby coral and damaging to adults in high concentrations, according the study published in the Archives of Environmental Contamination and Toxicology.

The international research team that conducted the study, led by Craig Downs, found the highest concentrations of oxybenzone around coral reefs popular with tourists, particularly those in Hawaii and the Caribbean.

Downs, of the non-profit scientific organization Haereticus Environmental Laboratory in Virginia, said the study helped explain why scientists aren't seeing baby corals in many established reefs in

resort areas.

Oxybenzone alters coral DNA, makes coral more susceptible to potentially fatal bleaching and acts as an endocrine disruptor, causing baby coral to encase itself in its own skeleton and die, according to the findings.

Between 6,000 and 14,000 tons of sunscreen lotion winds up in coral reef areas each year, much of which containing oxybenzone.

The damaging effects were seen in coral in concentrations of oxybenzone as low as 62 parts per trillion, which is equivalent to a drop of water in six and a half Olympic-sized swimming pools, according to the researchers.

In Hawaii and the Caribbean, concentrations were 12 times higher, according to the sea water testing.

Outside of coral toxins, the Environmental Working Group had previously raised concerns about the chemical, saying that it may penetrate the skin and cause hormonal and cellular changes.

The American Academy of Dermatology, says there is no data showing oxybenzone is a health hazard and notes that it is one of the few ingredients in sunscreen that effectively protects skin from harmful UVA and UVB rays.

Source: *The Times of India, 23rd October 2015*

Strides to Buy 7J & J Brands Majority Stake in Medispan

Strides Arcolab, an Indian drug manufacturer, has expanded its portfolio of offerings by acquiring brands from two companies in separate transactions.

Strides signed a deal with Johnson & Johnson to buy seven of its brands in the dermatology, antiemetic and pain management segments. The portfolio acquired from J&J includes Otogesic eardrops, Ehnorub ointment and Stugil tablets, Strides said in a statement to the stock exchange on Wednesday.

In a separate transaction, Bengaluru-based Strides said it will acquire a majority stake in the domestic branded businesses of Medispan, part of the Chennai-based Shriram Group, with a presence in probiotic, nutritional, anti-infective and gastrointestinal drugs. The brands that Strides will gain from Medispan include Lactovit and Lactogut.

The business in its entirety, including intellectual property and manpower, will be transferred to Strides Biologix Private Ltd., in which Strides.

Strides Biologix Private Ltd., in which Strides will hold 51%, the company said.

Strides did not disclose the deal value of the transactions. It said the acquired portfolios have a combined revenue potential of Rs 32 crore for 2015-16.

Strides Arcolab BSE -0.98 % has been on an acquisition drive to boost its presence in the growing market for branded generic drugs. Last month, Strides bought a set of products used to treat ailments related to the central nervous system from Sun Pharma BSE 1.14 % in a deal valued at Rs 165 crore.

Source: *The Economic Times, 23rd October 2015*

TIFR Team Comes up With Potential Malaria Vaccine

A fortnight after a Chinese doctor, TuYouyou, won the Nobel Prize in Medicine for her anti-malarial medicine, scientists from Mumbai's Tata Institute of Fundamental Research (TIFR) have published a research paper on their early success with a vaccine-candidate for malaria.

The TIFR team from Colaba identified a group of proteins present on the malaria-spreading plasmodium parasite, and combined their finding with some cutting-edge genetic and nanoparticle research, to produce antibodies in mice to ward off a malarial infection. The work is in early laboratory

work and may take years to reach human trials.

The need for a vaccine to control malaria has become important because of emerging resistance to existing anti-malarial pills. "There are over 30 malaria vaccine candidates across the world, with the first-ever vaccine set to start field trials in Africa," said the main researcher Dr Gotam Jarori whose work was published in Malaria Journal. "But our candidate-vaccine seems to have the broadest use as it could be effective against all strains of malaria," he said. The African trial vaccine, for instance, is known to offer more protection against cerebral malaria.

Malaria is a parasitic infection spread by mosquitoes, and is considered one of the biggest public health challenges as it kills half a million people across the globe every year. It's endemic in India, especially in coastal Mumbai, and cyclically re-emerges as one of the biggest killers. Mumbai was declared free of malaria in the seventies, but a difficult-to-diagnose/treat strain emerged late in the nineties. Between 2010 and 2012, the city witnessed one of the worst malaria outbreak in recent times, with over 250 lives lost and over tens of thousands affected in the period.

The TIFR team found a five-amino-acid segment that is of prime importance to the malarial parasite. "Each of the parasite's cells uses this protein to break down glucose into energy," said DrJarori.

His team has proven that this protein is important in spreading malarial cells to the host's red blood cells as well as within the vector mosquito's stomach. "Blocking this protein would thus control the disease's spread humans as well as break the transmission cycle among mosquitoes," he said.

The work was carried out in collaboration with the University of Maryland School of Medicine, Baltimore, whose scientists have special nanoparticles that were genetically fused with the protein segment. This was the vaccine-candidate that was then injected into mice. "We found that even a lethal strain of mouse malaria parasite in these vaccinated animals showed considerable protection against malaria," said DrJarori.

Dr K S Parthasarathy, former secretary of the Atomic Energy Regulatory Board, said, "This research is of great significance because it shows India's capability for frontal research. Moreover, it involves interdisciplinary work between TIFR and an American institution," he added.

Dr Jarori said that the work was still in early stages.

Source: *The Economic Times, 23rd October 2015*

Drug Cos Hit By FDA Woes Seek Common Brainstorming Arena

Indian drug companies that have been swamped by warnings and bans issued by the US Food and Drug Administration in recent years are planning to get together to exchange notes on how best to get out of such jams as they seek to protect exports to the world's biggest market for pharmaceuticals.

The idea is to address key issues related to quality, manufacturing and process compliance in order to identify solutions, several people aware of the development told ET.

Top executives of the largest Indian generic firms including Dr Reddy's Laboratories, Sun Pharmaceutical, Torrent Pharma, ZydusCadila and Lupin Pharmaceuticals met informally in Mumbai recently to discuss a common platform and brainstorm on ways of resolving FDA strictures. None of the companies mentioned responded to queries as of press time.

Although talks are still at "very nascent stages," specialists in manufacturing operations and quality

assurance told ET that the proposed grouping will share learnings on ensuring satisfactory inspections by FDA or other regulators besides dealing with import bans and warning letters. "The group will work toward benchmarking standards across industry giants," said an industry expert. He added, however, that the effectiveness of such an initiative would also depend on how freely ideas are exchanged among generic companies that are fierce rivals in the US market.

Taking this to the next level will have be widely significant since most leading drug makers such as Sun, Dr Reddy's, ZydusCadila and IPCA - which get more than half their revenue from the US - have been at the receiving end of harsh regulatory action by the US FDA on charges of violating globally mandated manufacturing standards.

The companies are discussing the formation of an expert committee and pooling specialists from areas such as high-end injectables, oral solids or liquids and ointments, one person told ET. This committee will oversee through sub-groups how companies implement corrective action, taking cues from companies that have passed regulatory scrutiny.

"We have many good examples of how companies have come out with zero observations from the FDA," said an executive at one of the companies involved in the new initiative. "This will lead the key discussions and experts from the shop floor will be roped in on how those conditions were met."

According to sector experts, Indian companies have seen US FDA notices on faulty process-related parameters as well those that are linked to lack of manpower training and skilling. Former bugbears such as data integrity are down but some deviations may have been registered due to unintended errors, perhaps due to entries made manually, according to this person.

Source: *The Economic Times, 24th October 2015*

Pill That Went From $13 to $ 750 Now Has A $1 Rival

In a demonstration of arbitrary pricing of medicines, pyremethamine, used to treat protozoal infections, went from $13 to $750 a pill in the US, an over 5,000% increase, and down to $1 per pill for a new version, all in a span of just over a month. The new $1 pill is being produced by a small San Diego-based company called Imprimis Pharmaceuticals.

Daraprim, or branded pyremethamine, was bought from its producer by Turing Pharmaceuticals owned by a hedge fund manager Martin Shkreli, who then hiked the price to $750 becoming "the poster child for big pharmaceutical greed". Despite widespread protest over the massive price hike of a 62-year-old off-patent drug, Shkreli failed to bring down the price after promising he would do so. Daraprim, which treats an uncommon parasitic infection, toxoplasmosis, is critical for treating immunocompromised patients of HIV/AIDS and cancer and also pregnant women.

Imprimis Pharmaceuticals is a compounding pharmacy, which in the US means a company which mixes approved drug ingredients to prepare medicines based on a doctor's prescription. This three-and-a-half year old company is producing a formulation of Daraprim's active ingredients, pyremethamine and leucovorin. The Imprimis formulation is not approved by the US Food and Drug Administration (FDA), but compounded formulations are allowed to be sold legally in the US as long as it is through a doctor's prescription. Compounding pharmacies do not need FDA approval unlike large pharma companies that mass produce drugs on complex production lines. The increasingly complicated regulations around FDA drug approval would have meant several years and millions of dollars for Imprimis and that would not have allowed it to keep the price affordable.

Source: *The Times of India, 25th October 2015*

CSIR Launches Rs 5 Herbal Drug to Fight Type-II Diabetes

A scientifically validated anti-diabetes herbal drug, named `BGR-34', was launched by a Council of Scientific and Industrial Research (CSIR) laboratory in Lucknow on Sunday .

A combination of natural extracts from plants, the drug is based on ayurveda and has no side effects. The drug is for management of type-II diabetes mellitus.

The drug has been jointly developed by two CSIR labs, the National Botanical Research Institute (NBRI) and the Central Institute for Medicinal and Aromatic Plant. It was launched on the NBRI's 62nd annual day for commercial manufacturing and marketing by MsAimilPharamaceuticalsPvt Ltd, New Delhi. The drug is likely to be priced at `500 for 100 tablets.

"The drug has extracts from four plants mentioned in ayurveda and that makes it safe," said Dr AKS Rawat, senior principal scientist, NBRI. It has been tested on animals and scientific study has found it safe and effective, with clinical trials showing 67% success. The drug boosts the immune system, works as an antioxidant and checks free radicals. Though there are other anti-diabetes herbal drugs in the market, `BGR-34' has been validated scientifically.

The formulation was launched earlier by VicePresident Hamid Ansari in February last year at Vigyan Bhavan, New Delhi, but on Sunday the product was launched commercially .

Source: *The Times of India, 26th October 2015*

Dr. Reddy's Lab Hit by FDA Warning

Dr Reddy's Laboratories Ltd, India's second-largest drugmaker, has received a "warning letter" from U.S. regulators over inadequate quality controls at three manufacturing plants producing drugs for cancer and other diseases.

The warning is the latest in a string of incidents that have hurt the industry's reputation and slowed its growth in the world's largest drug market, where India supplies more than 40 percent of the generic and over-the-counter medicines.

Dr Reddy's said the FDA warning meant it would not receive U.S. approvals for drugs made at the plants until it fixed the problems, a blow for business at a company which relies on the United States for a majority of its sales.

The affected plants account for more than 10 percent to 12 percent of the company's sales.

Dr Reddy's said a production halt may not be required, but the news caught investors by surprise, sending shares to their lowest in four months.

"We are probably looking at flat to declining earnings in FY 2017, while earlier we were expecting growth," said analyst Nimish Mehta, founder of Research Delta Advisors.

Analysts warned the move by the U.S. Food and

Drug Administration would hit U.S. sales for at least the next two years, as the launch of key products may be delayed.

"There is no indication in the warning letter that we need to stop manufacturing, but we will be examining the contents and deciding our strategy," Dr Reddy's Chief Finance Officer Saumen Chakraborty told Indian television news channel ET Now.

The FDA inspected the company's Srikakulam, Miryalaguda and Duvvada drug manufacturing sites in November, January and February, and almost immediately issued initial notices asking the group to rectify some problems.

But it was unable to fix the issues to the satisfaction of the FDA, and was hit with a warning letter. Such letters are issued by the agency when it finds a manufacturer has "significantly violated" its regulations.

"We had absolutely no idea it could escalate to this level," said SiddhanthKhandekar of ICICI Securities.

DATA RECORDS

Dr Reddy's said the agency's concerns with the plants related to quality control procedures and how data was recorded. It did not provide details.

The FDA has already banned plants of other Indian firms, such as Wockhardt Ltd and Ranbaxy Laboratories Ltd, a unit of the country's largest drugmaker Sun Pharmaceutical Industries Ltd, after finding faulty, fudged or incomplete data records in recent years.

Both companies have been unable to get their plants cleared by the agency, more than two years after the bans.

But analysts say the FDA considers data integrity issues to be the most serious, typically requiring at least two years to be remedied to its satisfaction.

Dr Reddy's Chief Executive G V Prasad said the group was revamping its quality systems as a result.

The FDA has increased the number of inspections of foreign plants supplying to the United States over the past year, exposing quality control issues at several Indian drugmakers. India plants of multinational drugmakers, such as Novartis and Mylan, have also come under fire.

Industry executives say they have been improving their manufacturing and systems, but sanctions continue.

Dr Reddy's makes drug ingredients at the Srikakulam and Miryalaguda plants, and cancer medicines at the Duvvada plant.

Source: *The Hindu, 7th November 2015*

Workers in Pharma Companies Receive Impressive Health Care

India's pharmaceutical companies seem to be giving more attention to the overall wellbeing of their workers compared to other sectors, with more than 70 per cent employees in the industry reporting good health in the workplace, says a report.

According to global health services company Cigna's survey of over 3,000 individuals in India, 73 per cent of the employees in the pharma industry reported good health and wellbeing in the workplace as compared to 54 per cent in the technology industry and 39 per cent in the retail sector. “Employees in the pharmaceutical, professional services and transportation report that they have good health and wellbeing in the workplace compared to those in manufacturing, telecommunications and retail,” Cigna said. Cigna has noted that with India witnessing economic growth, stress levels among its workforce are also increasing.

More than 60 per cent of the employees have

displayed some physical symptoms of stress like difficulty falling asleep at night or emotive symptoms such as failure to remember when they were happy.

Interestingly, the survey has found major gaps between what employees desire in medical benefits from employers and what their companies offer.

About 59 per cent of those surveyed want benefits for general practitioner consultation fees, while only 39 per cent say these are provided by employers. Additionally, 31 per cent of employees want benefits for X-rays, blood tests and other diagnostic tests, while only 20 per cent say their employers offer these facilities.

City-wise, employees in the non-metro cities reported having less stress than those in the metro cities.

They are better compensated and have reasonable working hours.

As many as 75 percent of employees residing in non mega cities felt they had little work related stress compared to 66 percent living in metro cities. A large number of employees in Lucknow, Surat, Mumbai and Bangalore felt they have little work related stress, the survey said. Among women respondents, those between aged 25 and 29 years delayed having children due to pressure from work, while those in the 30-39 age group gave financial implication of raising children as major reason for the delay.

Source: *The Hindu, 12th November 2015*

Government to Ease Testing Norms for Drugs Approved Abroad

India has taken a series of steps aimed at easing rules for tests and clinical trials needed before the introduction of drugs that have already been approved in other countries.

The move places greater responsibility on the ethics committee that vets clinical trials and is expected to cut timelines for the launch of new medicines, including biologics. The Central Drug Standard Control Organization (CDSCO) notified the changes through a November 10 circular.

If a new drug has already been approved outside India after pre-clinical and toxicological studies on animals, they don't need to be repeated for approvals related to imports or local manufacture unless specific concerns are raised.

The move follows meetings in August and October at the health ministry. The industry has been lobbying for long against repeat tests and data submissions. The regulator has been cautious about approving new drug trials against the backdrop of a court case that has pointed to the agency's inadequacies in this regard.

The Investigational New Drug Committee and Drug Technical Advisory Board set up by the health ministry had recommended that the norms for additional tests be eased.

In another decision, the Drug Controller General of India (DCGI) has allowed the ethics committee to add trial sites and investigators after due diligence.

The committee won't need a no-objection certificate (NOC) from the DCGI under normal circumstances, it said in a circular. However, the applicant will need to provide information about any additions or deletions. If an NOC is received from the DCGI, it will be deemed to have the concurrence of the CDSCO as it comes under the latter's purview.

Through a separate circular, the regulator also allowed companies to submit parallel applications to the Review Committee on Genetic Manipulation, under the department of biotechnology, and the DCGI for seeking approval of biologic products such as insulin and monoclonal antibodies

Source: *The Economic Times, 12th November 2015*

India to Push for Acceptance of Desi Drug Norms Abroad

The Indian government is lobbying with certain unregulated markets to accept Indian Pharmacopoeia, realizing that most domestic drug makers cannot upgrade their manufacturing facilities to global standards set by the US FDA for exporting medicines.

India's commerce ministry is in talks with at least 10 such unregulated economies and will have a detailed meeting with their regulators and enforcement authorities next month to impress upon them about the superior Indian drug standards. These countries include Vietnam, Cambodia, Myanmar, Iran, Ukraine, Belarus, Ghana, Nigeria, South Africa and Kenya among others.

A top commerce ministry official said a meeting of regulators and enforcement authorities of these 10 odd unregulated economies would take place at Mysore next month. "These markets are currently accepting either the British Pharmacopoeia (BP) or the United States Pharmacopoeia (USP) while sourcing medicines from India," Director-General of Pharmaceuticals Export Promotion Council (Pharmexcil) PV Appaji told ET.

"If we are successful in convincing these markets to accept the Indian Pharmacopoeia (IP), then it helps many Indian medicine manufacturers, which are solely following IP, to save significantly on time, packaging and other costs needed to adopt either BP or USP."

Pharmacopoeia is a set of standards and quality specifications for ingredients, preparation and dosage forms of medicines manufactured, sold, consumed and exported in a country. According to information on World Health Organization's website, there are 140 independent countries that are currently adopting around 30 national and African, European and International Pharmacopoeias.

India exported around $15.2 billion (approximately Rs 95,000 crore) of medicines last fiscal and these 10 unregulated markets accounted for nearly $2 billion.

Appaji said the representatives of the regulators and enforcement authorities of these 10 countries would be participating in the ensuing Indian Pharmaceutical Congress at Mysore in December.

We have lined up an exclusive meeting on the sidelines of the Congress to discuss various regulatory issues, including the proposal to convince them to allow IP. If successful, it enables a number of domestic drugmakers to begin shipments and thereby help the country significantly improve its overall exports."

India is looking at convening similar meetings with more unregulated countries based on the success of the December meeting said Appaji.

Source: *The Economic Times, 25th November 2015*

Roche Launches Costliest Cancer Drugs in India

Kadcyla and Perjeta cost Rs 2.1 lakh (200 ml) and Rs 2.4 lakh for a dosage respectively

As insurers, patients and governments across the world debate over the rising cost of healthcare, Swiss pharmaceutical major Roche has boldly launched two new drugs for late-stage breast cancer, pricing them higher than any other cancer medicine in the Indian market.

Kadcyla and Perjeta, the new class of drugs launched in India in October, cost Rs 2,10,000 (200 ml) and Rs 2,49,000 for a dosage, respectively. ET verified the price with several chemists and doctors, who said the maximum discount that was available was in the range of Rs 10,000-15,000. Roche said it gives the drugs free of cost after an initial stage of treatment.

Breast cancer is the leading cause of cancer death among Indian women. Nearly 1.3 lakh women are diagnosed every year with the disease in India. Kadcyla and Perjeta are prescribed for breast cancer patients tested positive for the HER2

protein, which promotes the growth of cancer cells.

These drugs are given when the cancer becomes metastatic, or in simple terms when the tumour spreads to other parts of the body where the chances of cure are negligible. They are recommended when patients fail to respond to Herceptin (trastuzumab), the most commonly prescribed treatment for breast cancer.

The cost of the drugs over a nine-month period hovers around Rs 12 lakh for Kadcyla and Rs 30 lakh for Perjeta. In India, Roche collaborated with Pune-based Emcure Pharmaceuticals to sell Herceptin under a local brand name, Herclon, which costs about Rs 65,000 a vial.

Responding to ET's questions, Roche said it has a patient assistance programme aimed at lowering the cost of treatment. "We at Roche believe that access programmes need to be sustainable in order to have a long-lasting impact," the company said in an email response. "Our patient-assistance programme for Perjeta and Kadcyla is designed such that patients only have to pay for finite cycles of therapy and hence the total cost is significantly lowered," a Roche spokesperson said in an email response to ET.

Incidentally, last week, the National Institute of Health Care and Excellence (NICE), an agency that is involved in guiding healthcare improvement, has advised UK's National Health Service against including Kadcyla in its reimbursement scheme citing a mismatch between price and value.

The Indian government itself has taken note of high-priced cancer drugs and signalled controls over those. More recently, Union Health Minister JP Nadda unveiled the first outlet to supply low-cost cancer drugs at the All India Institute of Medical Sciences in New Delhi. Oncologists in India expressed their concerns over the high price tag that these drugs came attached with.

"These newer drugs are prescribed after Herceptin fails. Any failure has no cure. So I have to tell the patients that you might be getting three months of extra life for spending Rs 20 lakh," said Dr Rajendra Badwe, surgical oncologist at Mumbai's Tata Memorial Cancer Hospital (TMC). "It is a value judgement that needs to be done, and the care giver is put into a big dilemma of decision-making."

A leading oncologist from a public hospital in south India said he has not encouraged patients to get on these drugs because of the price. "My patients here cannot even afford Herceptin, so we have made it clear to the patients about the price and the results that these drugs deliver," said this oncologist who spoke on the condition of anonymity.

Kadcyla and Perjeta were approved by the US health regulator in 2013, after trial results suggested an increased rate of survival in late-stage patients compared with existing line of therapy.

Source: *The Economic Times, 26th November 2015*

Drug to Treat Skin Cancer in the Offing

Scientists have discovered a new drug that shows promise for treating deadly forms of skin cancer, such as melanoma, which are resistant to existing therapies.

The new compound, named SBI-756, targets a specific molecular machine known as the translation initiation complex.

These structures are in every cell and play the critical role of translating messenger RNA (mRNA) into proteins. In cancer cells the complex is impaired, producing extra protein and providing a growth advantage to tumours.

SBI-756 causes the translation complex to dissociate, and inhibit melanoma cell growth.

"A major issue limiting the effectiveness of current melanoma therapies is that tumours become resistant to treatment," said Ze'ev Ronai from Sanford Burnham Prebys Medical Discovery

Institute (SBP) in US.

“Combining drugs that come at a melanoma from different angles may help overcome the problem of drug resistance," said Ronai.

About 50 per cent of melanomas are caused by mutations in a specific gene called BRAF. Patients with these tumours are commonly prescribed vemurafenib, a BRAF inhibitor that shrinks tumours.

Source: *The Times of India, 27th November 2015*

HC Bench Upholds Roche’s Patent Claims on Tarceva Against Cipla

A division bench of the Delhi High Court sided with Roche against Indian firm Cipla, upholding the Swiss drug maker's patent claims on key lung cancer drug erlotinib hydrochloride, branded Tarceva. The ruling is the second in a month to have upheld patent rights of an overseas drug company and sets a key precedent with regard to intellectual property, experts said.

The court, however, rejected Roche's plea for an injunction on Cipla's product, considering the patent expires in March 2016. Roche, which was granted a patent for Tarceva in 2007, sued Cipla in 2008 after the Indian company launched cheaper version Erlocip. Cipla said it hadn't infringed the innovator's patent as it sold a polymorphic form of the drug.

Legal experts noted that Cipla may appeal against the decision of the division bench to the Supreme Court but this could not be confirmed from the company. In its latest order, the court directed Cipla to pay Rs 5 lakh while adding that it will be liable to render accounts concerning the manufacture and sale of Erlocip "to record evidence pertaining to the profits made by Cipla concerning the offending product."

In a statement to ET, Roche said it welcomed the decision of the court, which has upheld the patent covering erlotinib hydrochloride (Tarceva) and found Cipla to have infringed it.

The latest decision sets aside a 2009 verdict by a single judge in the same court that had rejected Roche's arguments and allowed the Indian drug firm to continue selling its product.

Roche and Cipla then cross appealed against that decision and last year, on directions from court, the two had agreed to discuss a settlement via a mediation exercise. However, an amicable settlement remained elusive and the case moved back to court. In a 106-page order, Justices Pradeep Nandarajog and Mukta Gupta outlined contentions of the two sides. The court was clear about nature of infringement.

"This (the patent claim) is a sufficiently broad claim that is clearly not limited to any polymorphic version of erlotinib hydrochloride, but to erlotinib hydrochloride itself," it said. "This compound may exist in several polymorphic forms, but any and all such forms will be subsumed within this patent. Therefore as Cipla's Erlocip is admittedly one particular polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will clearly infringe IN'774 patent."

Roche had said its patent covered all polymorphs and derivatives of erlotinib while Cipla contended its product (polymorph B) didn't infringe Roche's intellectual property. Cipla had also demanded Roche's patent be revoked under Section 3(d) of the Indian Patent Act that essentially bars incremental innovations unless significant efficacy is proven.

Bringing clarity to Section 3(d), the judges wrote: "We understand Section 3(d) as a positive provision that in fact recognizes incremental innovation while

cautioning that the incremental steps may sometimes be so little that the resultant product is no different from the original. The inherent assumption in this is that infringement of the resultant product would therefore be an infringement of the original i.e. the known substance and by no stretch of imagination can Section 3(d) be interpreted as constituting a defence to infringement." Last month, Merck had won a crucial case related to anti-diabetes drug sitagliptin against Indian drug maker Glenmark.

Source: *The Economic Times, 28th November 2015*

Biocon's Revenue Could Hit $1 Billion in 4 Years

India's biggest biotech firm Biocon Ltd expects revenue to double to $1 billion in four years as it expands in Europe and the United States with new products, its chairperson and managing director said on Saturday.

In a tie-up with U.S. generic drugmaker Mylan NV, the Bengaluru-based biopharmaceutical firm has five biosimilar products - almost identical copies of original drugs - entering global regulatory approval stage which is expected to take about 18-20 months.

"We forecast that by financial year 2019 our revenues will be $1 billion with 25 per cent coming from research and 75 per cent from rest of our business," Kiran Mazumdar-Shaw told Reuters on a business visit to Abu Dhabi.

Biocon's revenues were a little less than $500 million for fiscal 2014-15, she said.

Of the 70 per cent of the products that it exports, the United States and Europe account for 50 per cent.

Biocon has invested over $200 million in research and development to develop biosimilars at its Malaysia facility, currently in its commissioning phase, she said.

The firm has lost business in some Middle East markets due to turmoil in the region, particularly Syria where Biocon had high sales.

Sales in Lebanon, Egypt and Iran also fell but there were signs of recovery in Egypt, said Shaw, who started Biocon out of a garage in 1978 in Bangalore.

She declined to give specific sales figures for Syria or the other Middle East markets. The Middle East and north Africa markets account for about 6 per cent of Biocon's exports.

To offset those markets, Biocon has been focusing through aggressive marketing in north African markets such as Algeria, Morocco and Tunisia as well as markets in central and south-east Asia and Latin America.

Shaw also said Biocon could divest further in its research and manufacturing arm Syngene in 2016 once the latter reaches strong growth.

"It won't happen this fiscal, we are looking at next year," she said without giving details.

Source: *The Hindu, 30th November 2015*

Correction in Pharma Calls for Caution

After a 4-year-long rally, Pharma stocks have not witnessed much movement the last 6 months. Experts say investors should be cautious. "The sector is in correction mode and the derating may continue for some time," says Surajit Pal, Pharma Analyst at Prabhudas Lilladher. There are multiple factors triggering the correction. First, any warning from the US Food and Drug Administration (FDA) can pull down a counter immediately. Dr Reddy's Lab is a case in point. High valuations is the second reason.

"Though the sector in India has huge cost advantage over pharma companies in the

developed world, valuations are rich for all good companies," says V.K. Vijayakumar, Investment Strategist, Geojit BNP Paribas. As it was reporting regular growth rates in the past, valuations in the sector started aligning with the consumer sector. However, the pharma sector can't have consumer sector valuations because there is a regulatory risk involved in pharma.

Moderation in growth rate is the third factor. "Most large-cap pharma stocks have reached high base and therefore, may not be able to match historical high growth rates," says Pal. Indian pharma exports grew on the back of a large number of drugs going off patent in the US. Since the number of such drugs is now coming down, export growth rate may also moderate.

What should investors do now? Says Suhas Harinarayanan, Head of Research, JM Financial, "We like most pharma stocks. However, we are underweight on them in our model portfolio and would advocate a more stock specific approach at the moment." So, there is no need for investors to avoid all pharma exporters. What they need to do is to select only stocks that have exposure to the drugs going off patent in the near future.

Similarly, investors also need to take a look at companies facing headwinds. Sun Pharma is facing integration problems after acquiring Ranbaxy. The FDA related problems for Dr Reddys Lab has only started. Since pharma companies take 9-12 months to set right the problems pointed out by FDA, the sales and net profit growth of Dr Reddy's Lab may be muted for the next 3-4 quarters.

Unlike diversified equity funds, where you can keep on investing for long periods, investors need to be more proactive in sector funds. This is because sector preferences keep changing. Pharma funds have generated great returns in the last few years. Investors with portfolios tilted towards the pharma sector need to book partial profit and reduce weight.

Investors who want to maintain weight in pharma should also consider booking some profit and re-enter using systemic transfer plans (STPs). Investors who have got into the sector only recently can continue with SIPs. The STPs and SIPs will help investors benefit from the expected correction, by getting more units at lower NAVs.

Source: *The Economic Times Wealth, 30th November – 6th December 2015*

This Diabetes Drug could let US Live Past 120

Clinical trials have started for a miracle drug that could help us live into their 120s. The Food and Drug Administration in America has given the green light to the trials of cheap drug metformin, which is used to treat people with type 2 diabetes, on older people, the Daily Express reported.

The pill's developers hope that it could one day wipe out diseases like Alzheimer's and that they can slow down the ageing process in humans, making those in their 70s as healthy a 50-year-old.

"If you target an ageing process and you slow down ageing then you slow down all the diseases and pathology of ageing as well," said ageing expert Prof Gordon Lithgow, of the Buck Institute for Research on Ageing in California, and one of the study advisers reported ANI.

Researchers have already proven that the diabetes drug metformin extends the life of animals. Now experts want to see if the same effects can be replicated in humans.

Last year researchers at Cardiff University found that when patients with diabetes were given the drug they lived longer than others without the condition, even though they should have died eight years earlier on average.

The trials are expected to take five to seven years. The drug will aim to attack the process of ageing, rather than individual diseases, one of the project's members, Stuart Jay Olshansky, has explained.

Source: *The Economic Times, 1st December 2015*

Indian Drugmakers Launch Low-price Diabetes Medicine

Low-priced drugs with fewer side effects will change the treatment method: experts

Dozens of Indian drugmakers have launched cut-price versions of teneligliptin, a new generation medicine for type 2 diabetes patients.

Costing a fraction of the brands sold by global organizations and their local affiliates, medical experts say the strengthening trend of new, low-priced drugs with fewer side effects may fundamentally change the way the disease is treated.

Against the average price of Rs 42 per tablet for brands marketed by global companies, Indian firms including Zydus Cadila, Mankind, Ajanta Pharma, Wockhardt, Intas, Alembic and Unichem sell their products in the same class at prices ranging from Rs 7 to Rs 19.90 per tablet.

There are over 16 brands in this new market and sales have touched Rs 24 crore in the past six months, according to AIOCD PharmaTrac, a local pharmaceutical market research firm. Glenmark was the first off the block in July with a dual branding strategy of Ziten Rs 19.90 a tab and Zita Plus drugs priced at less. Last week, the company slashed the Rs 9.90 per tablet. Data show the price of combined sales of the two brands touched about Rs 18 crore.

The launch of the drugs played a major role in significantly reducing the price of treating diabetes in the country, said Glenn Saldanha, Chairman of Glenmark Pharma. Being the first to hit the market, Glenmark said it needed the mark said it needed the backing of robust clinical trial data.

The company conducted a random, double blind, placebo-controlled multi-centre study to evaluate the safety and efficacy of teneligliptin in patients over two years across 24 sites in India.

Clinical trial experts noted that the data generated by Glenmark may have helped the raft of Indian regulatory approvals for other companies.

Last month, Ahmedabad-based Zydus Cadila claimed Tenglyn, priced at Rs 7 per tablet, would be the cheapest in Indian Market experts believe prices may stabilize at this level.

Mankind Pharma, which sells the drug branded Dynaglipt, is targeting the middle class and rural diabetic patients.

Source: *The Economic times, 16th December 2015*

Bionpharma Buys 25 Products from Banner Life Sciences

Bionpharma, a New Jersey-based pharmaceutical startup founded last year by five former Ranbaxy executives and backed by strategic and financial investors, has acquired a portfolio of approximately 25 products from specialty drug maker Banner Life Sciences.

The combined revenue of the acquired products is estimated at more than $70 million and forms a mix of high-potency steroidal, antiviral, neurology, over-the-counter pain management and anti-allergy medicines. Banner sold the products to focus on developing specialised drugs, experts said. Of the products acquired by Bionpharma, 18 are marketed as generic drugs, four are specialised products filed as NDAs (new drug applications) with the US Food and Drug Administration, two are in the process of regulatory reviews and two are undergoing development.

Some of the drugs that will be part of Bionpharma's portfolio include cetirizine and ibuprofen sold over the counter in the US but are on NDAs as they are sold under a differentiated formulation. One of the specialised drugs acquired is a soft gelatin form of loperamide used to treat diarrhea. Some of the products are distributed by partners such as Impax and Mylan.

CEO Venkat Krishnan, who led Ranbaxy's US operations before leaving the company last October, confirmed closure of the deal but did not

divulge the value of the transaction.

Bionpharma has launched four products in the US through in-licensing deals — a form of joint development — with other companies. It has partnerships with global pharmaceutical companies, including a few from India such as Natco and Unimark Remedies. Krishnan told ET his company is seeking more opportunities to scale up, adding that the right mix of products and a clear business strategy with a secure and compliant supply chain can help accelerate growth. He indicated that Bionpharma may consider establishing a manufacturing base in the future.

The deal with Banner is expected to help jump start Bionpharma in the crowded generics space. Over the past 12 months, the company has seen a flurry of investments. New York-based global investment firm Signet Healthcare owns more than 40 per cent of the company while one of Canada's largest drug makers, Pharma Science, holds another chunk of equity. Krishnan, Gaurav Mehrotra, Bill Winter, Lavesh Samtani and Phanindranath Punji— all of whom quit Ranbaxy in October last year — form the third largest group of shareholders.

Source: *The Economic Times, 21st December 2015*

Biggies Under USFDA Lense, India Cos May Face More Scrutiny

Domestic drug companies will face increased scrutiny from global regulatory agencies, including the US Food and Drug Administration (USFDA), with the top two companies Sun Pharma and Dr Reddy's now under regulatory glare. Sun Pharma joined the long list of companies last week against whom warning letters have been issued this year, while in November the USFDA raised concerns on Dr Reddy's manufacturing practices at three of its plants.

A total of seven companies have been issued warning letters this year by the US regulator, raising issues of manufacturing lapses at their facilities in India. Indian companies will continue to be under FDA observation, with a higher number of inspections. "This (warning letter) is a cause of worry as serious manufacturing lapses have been pointed out by the regulator," says Sujay Shetty, leader (pharma), PwC India, says. At present, 38-40 investigations are on at more than 25 companies across the country.

India accounts for around 30% (by volume) and about 10% (value) in the $70-80 billion US generic market. Over the years, India has become a dominant player in the US generic space, with a large number of plants and increased scale of operations, exporting key drugs and injectables from the country. "Now there's increased pressure on domestic companies, and an intense scrutiny from the US FDA and other regulatory agencies globally, post two large companies having come under FDA action. We will need to perk up," says an executive working with a large industry player.

Usually, the regulator's action has an adverse impact on the company for a few quarters. But analysts say most companies are able to resolve the issues over two to three years. An analysis of the period 2009-12 suggests domestic companies received 13 warning letters, of which eight (61%) were resolved, with six of those being resolved within two years.

WHAT LED TO WARNINGS

Co	Plant	Manufacturing issue
Dr Reddy's	2 in AP, 1 in Telangana	Raw materials (APIs)
Unimark Remedies	Gujarat	Raw materials (APIs)
Pan Drugs	Gujarat	Raw materials (APIs)
Sipra Labs	Telangana	Finished formulations & raw materials (APIs)
Mahendra Chemicals	Gujarat	Raw materials (APIs)
Cadila Pharma	Gujarat	Raw materials (APIs)
Micro Labs	Goa	Finished formulations

API: Active pharmaceutical ingredients — Source: USFDA website

Domestic companies have been quick to devise strategies by reducing dependence on the affected facility, once they face regulatory action, says Sarabjit Kour Nangra, VP (Research-Pharma), Angel Broking. Sun Pharma, for example, received an FDA approval to launch a key drug, the generic Gleevec with market exclusivity, from another US subsidiary.

In this environment, Indian companies need to improve learning processes systematically and vigorously. D G Shah, Secretary General, Indian Pharmaceutical Alliance, says, "We are in dialogue with the USFDA to train our companies to meet the specified norms. What US and Europe faced 10 years back, India is facing now. There is no issue with product quality with domestic generic drugs, but what needs to be followed strictly is documentation and processing at the manufacturing facilities."

Source: *The Times of India, 22nd December 2015*

Sun Pharma Needs to Fix leaking Roof, Contamination Risks at Halol: USFDA

A leaking roof, walls that weren't smooth enough to be cleaned easily, the possibility of microbial contamination, inadequacies in airflow systems and the absence of a comprehensive assessment of informal investigations. That's why the US Food and Drug Administration issued a warning to Sun Pharmaceutical Industries 15 months after inspectors visited the Halol plant, one of the company's largest manufacturing sites. The reasons are listed in the letter that the FDA sent to India's biggest drug maker. ET has seen a copy of the letter, which even refers to buckets being used to collect leaking water.

The FDA has directed Sun Pharma to systematically improve the oversight of manufacturing quality to ensure sustainable quality assurance. The warning letter of December 17, based on the inspection between September 8 and 19, 2014, cites several deficiencies in the methods used in the facilities or controls used for manufacturing, processing and packing that did not conform to good manufacturing practices.

However, the letter does not point to any data integrity issues, which can be termed as a "major positive," said a market expert. The FDA letter said the agency reviewed Sun's October 10, 2014, response in detail adding that it "lacked sufficient corrective actions." Following that, Sun had submitted additional documents on December 12, 2014, February 10, 2015, and May 5, 2015. The regulator had posted its letter on the FDA site but this was subsequently removed. The agency said Sun failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that included validation of all aseptic and sterilization processes.

"You failed to perform adequate unidirectional airflow studies (smoke studies) under dynamic conditions to determine how the movement of air and personnel during aseptic operations could pose risks to product sterility. In addition, the studies indicate that your aseptic processing equipment is not properly designed," said the letter, signed by Thomas Cosgrove, director, Office of Manufacturing Quality, Center of Drug Evaluation Research.

The FDA directed the company to "perform and send a video of new dynamic smoke studies that fully evaluate unidirectional airflow during your aseptic manufacturing operations, and a copy of your revised smoke test. Also explain how your firm will be comprehensively evaluating the design of your aseptic processing operation, and describe

any major equipment and facility upgrades that are planned."

On specific issues related to filling of vials, the FDA letter noted Sun Pharma should include risk assessment regarding the practice of rejecting media-filled vials without written justification and acceptance limits. The FDA has called for a revised SOP (standard operating procedure) on media fills, specifically addressing the changes made relating to rejection and investigation of non-integral vials.

Making particular reference to the quality of floors, walls, and ceilings in the aseptic processing area, the FDA said they were not maintained as "smooth, hard surfaces that were easily cleaned."

The US FDA said, "Our investigator documented the presence of leaks in the form of water stains and ceiling damage in the parenteral manufacturing area personnel corridor. The FDA investigator observed buckets with water collected from ceiling leaks and other leaks in this manufacturing area."

Source: *The Economic Times, 24th December 2015*

M & A s Peak in Pharma Industry

Facing an increasingly watchful eye of the health regulator in the US, Indian pharmaceutical firms are gearing up to tap new markets in 2016 as they look to consolidate their positions after a spate of mergers and acquisitions consummated this year.

Globally also, it remained a year marked with record mergers, led by the $160 billion deal between Viagra maker Pfizer Inc and Botox manufacturer Allergan.

These deals came at a time when the domestic pharma firms continued to remain under intense regulatory spotlight, specially of the US Food and Drug Authority (FDA), while they stared at yet another challenge domestically over possibility of prices of more drugs coming under government control.

The biggest of the deal came from Pfizer which stitched a $160 billion deal to take over Allergan. Creating a global pharmaceutical behemoth.

It wasn't Pfizer's only deal -- the US giant also bought Hospira Inc, a leading provider of injectable drugs, infusion technologies and biosimilars, in a $17 billion deal.

Indian firms, including Sun Pharma, Cipla and Lupin, too took the acquisition path in their quest for international footprint expansion.

The biggest acquisition by an Indian firm in 2015 was by Lupin which agreed to pay $880 million (over Rs 5,610 crore) to take control of US-based Gavis. Drug major Sun Pharma also inked deal of over $48 million to acquire US-based eye-care firm InSite.

Another homegrown pharma major Cipla also paid $26 million (around Rs 166 crore) upfront to acquire majority stake in Uganda's Quality Chemicals.

Reflecting on implications of the events of 2015, Novartis India Vice Chairman and MD Ranjit Shahani, who was earlier the President of industry body OPPI, told PTI: "As pharma companies globally look at consolidating in some way or the other, Indian pharma firms would do well to negotiate the new pharma landscape. It will also provide them the opportunity to actually benefit from spin-offs."

Almost an year after announcing a $4 billion deal, Sun Pharma completed the merger of Ranbaxy with itself. The deal fortified Sun's position as the world's fifth largest specialty generic pharmaceutical firm and the top ranking Indian pharma company with significant lead in market share.

In contrast, Japanese drug maker Daiichi Sankyo sold its entire stake of around 9 per cent in Sun Pharma for over Rs 20,420 crore, which it had received after merger of Ranbaxy with the Indian

firm, ending its seven years of tumultuous experience in the country.

On the regulatory front, the year witnessed many Indian firms coming under the scanner of the regulator in the US, which remains a key market for Indian generic drugmakers.

Sun Pharma was forced to take remedial action at its Halol facility for lapses in manufacturing norms and was given a warning letter for the same. Earlier its another plant at Karkhadi, also in Gujarat, had received a warning letter from the USFDA after investigators found similar violations.

Hyderabad-based Dr Reddy's Laboratories also received a warning letter from the US drug regulator over quality issues at its two API manufacturing plants and a formulation unit in Andhra Pradesh and Telangana.

"Pharmaceutical companies will have to gear up to meet the increasingly watchful eye of the USFDA and this is bound to have an impact in the near term for companies who export heavily to the US," Shahani said.

Wockhardt had to recall 13 drugs in the US, manufactured at its two units at Chikalthana and Waluj in Maharashtra, which were under import restrictions from the USFDA.

In the US, Cipla also recalled 1.41 lakh vials of Levalbuterol Inhalation solution used for relieving shortness of breath and coughing caused by asthma and chronic obstructive pulmonary disease for failed impurities and degradation specifications.

Likewise, Mylan got a warning letter from the USFDA for violation of current good manufacturing practice (CGMP) norms at its three plants in Karnataka.

Drug maker Sharon Bio-medicine was issued a warning letter by the USFDA for failing to pay generic drug user fee by its owner for three years starting 2013, saying its Dehradun-based facility would be barred from shipping products to the US if the dues are not cleared.

"Unless the major companies are successful in expeditious resolution of regulatory issues, the developed markets will continue to hurt the growth. The opening up of Japanese generic market and focus on the Latin America and Africa may bring some relief," Indian Pharmaceutical Alliance Secretary General D G Shah told PTI.

The year also saw the government making an attempt to expand drugs under price control by revising the National List of Essential Medicines which the industry felt would hamper growth of the sector.

Despite the odds, said Shah 2015 is expected to end with about 15 per cent domestic market growth.

"The volume and value are consistent with the character of the generic industry...But new products growth is grossly below its potential.

This is mainly due to slowdown in marketing approvals during the preceding two-year period and delay/denial of price approvals by the NPPA for new products during 2015," he said.

On expectations of the next year, Shah said 2016 is expected to maintain the current year's growth rate in the domestic market, against its potential of about 18 per cent growth.

"This below potential growth is due to the change over to the NLEM 2015, which will enlarge the span of control adversely impacting value growth. It may in fact have negative impact. Besides, intense competition will lead to price erosion," he added.

The government, on its part, took steps such as measures to improve bulk drug manufacturing in India to reduce dependence on China; planning a separate ministry for pharmaceuticals sector to boost the domestic industry.

It also brought in the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) effective till January 2016, for ethical marketing.

Source: *The Hindu, 25th December 2015*

On a Threshold of Drug Innovation

Indian drug maker Wockhardt has quietly been conducting discovery research in a narrow range of potent anti-infective compounds, which, if successfully developed, promise to fight life-threatening pathogens and vindicate the company's perseverance in staying on course through the past two decades.

The signs have been encouraging, although late in terms of the lengthy drug development cycle. Over the past 15 months, the US Food and Drug Administration has granted four of Wockhardt's experimental antibiotic drugs a priority review status called Qualified Infectious Disease Product (QIDP), which accelerates the drug development cycle in addition to providing a five-year extension of the exclusivity period, post approval.

This has fuelled Wockhardt's ambitions to go full throttle into further developing the drugs, vaulting it into the pack of A-listers of select global drug makers including Roche, Merck, Pfizer and AstraZeneca that have stepped up interest in the same area lately. Wockhardt increased its investment in research & development to 11.5% of sales during FY15 at Rs 515 crore from 9.3% of sales in FY14 at Rs 450 crore.

Although the risks of late-stage failures cannot be ruled out, the low-profile yet ambitious leads have shown safety and effectiveness in treating bacterial infections such as klebsiella (a form of pneumonia), MRSA (methicillin-resistant staphylococcus aureus) and metallo beta lactamase, among others. International experts forecast that these infections can invariably lead to catastrophic medical consequences if no timely treatment options are developed.

Somewhat coincidentally, Wockhardt's pipeline is maturing at the right time. The FDA's initiative on faster approvals, enacted as part of the Generating Antibiotic Incentives Now (GAIN) Act of 2012, underlined the urgency to develop new antibiotics. Against roughly 18 approvals for antibiotic drugs

granted by the FDA between 1980 and 1984, data culled from prominent scientific journals suggest the number dwindled to six between 2010 and 2014.

So far, the US regulator has granted QIDP status to about 35 products and encouragingly, the list is expanding. Wockhardt is upbeat about the prospects of the compounds in the pipeline, Chairman Habil Khorakiwala, 73, told ET. Although a market launch may be three to four years away, the company has tasked management consulting firm McKinsey & Co. with evaluating the potential of the drugs once they reach the last mile of regulatory clearance and commercialization.

In the near term, Wockhardt plans to accelerate the development of its earliest lead called WCK 771 - an intravenous injection - into phase III clinical studies. The drug's efficacy will be tested on a large set of patients in select international markets.

Khorakiwala noted that WCK 771 will be targeted primarily at emerging markets and if conditions are suitable, the company may explore local partnerships since it may not have the capability to conduct studies and take up regulatory filings at the local level. Another compound, WCK 2349, delivered in oral form, offers significant benefits over its peers as most products currently under development are delivered to patients as injections.

For another set of drugs - WCK 4873, WCK5222 - Wockhardt plans to go solo in conducting global studies. Khorakiwala categorically said he has no plans to out-license his products. Filing for registration of the drugs in the US and Europe will form an important step in the overall game plan. For Wockhardt, the renewed optimism in the global outlook for anti-infective products vindicates its long-term strategy. Choosing anti infective drugs was not an impromptu decision.

Khorakiwala recalls his visits to some leading research facilities of large global drug makers to evaluate their potential and risks. The interest at that time was waning, he said, but the market dynamics still looked favourable and two decades later, his contrarian bet may prove to be right.

"Antibiotics formed about 25% of the (pharmaceutical industry) turnover in emerging markets like India and China. From a pure competitive analysis, there was hope of a product either for the global market or at least for the emerging market and that was our conceptual framework. We stuck to our core over the last two decades and we did not get into any other areas," he remarked.

Researching anti-infective drugs was considered less commercially viable than products for neurology, respiratory or oncology disorders. The price of cancer drugs jumped, while those of antibiotics stayed in a low band. Further, with pathogens mutating rapidly, newly approved drugs were fraught with the risk of becoming resistant and losing their effectiveness.

Sensing the impending crisis, the Centers for Disease Control and Prevention, the top US health agency, declared in 2013 that the human race is now in the "post antibiotic era" and a year later, the World Health Organization sent out a stern cautionary signal that the crisis of antibiotic resistance is becoming dire. MRSA causes the death of an average 11,285 patients a year in the US alone, recent data showed. With the alarming rise in the incidence of drug resistant infections, multinational pharma companies are signing up deals at a fast clip.

In January 2015, Swiss giant Roche struck a $750 million deal with Japan's Meiji Seika for an earlystage compound to battle multiple drugresistant infections. A month before that, US major Merck & Co. lapped up antibiotic specialist Cubist in a $9.5 billion merger to spruce up its antimicrobial research programme.

In February 2015, Anglo-Swedish drug maker AstraZeneca said it will spend $40 million to create a new stand-alone subsidiary focused on early stage R&D of small molecule anti-infective drugs. Last June, New York-headquartered behemoth Pfizer said it will spend as much as $1.9 billion to acquire Vicuron, a company developing novel antiinfective drugs for hospital-based and community acquired infections.

Not to rest on its four aces, Wockhardt is matching up globally. Khorakiwala said the regulators have approved an abridged pathway for his drugs but his company will continue to seek new leads in the sphere of anti-infective drugs.

Source: *The Economic Times, 9th January 2016*