ISSUE No. 13

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2012

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Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

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ISSUE : 13 Jan. - Feb. - Mar. 2012

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EDITORIAL

Dear Readers,

This is the 13th issue of our quarterly Newsletter since inception. Our new Chairman, Mr. S. V. Veerramani, Managing Director of Fourrts India Private Limited, Chennai initiated important activities like essay competition for the final year B. Pharm students and also to organize a full day seminar on **"Documentation for Export of Drugs and Pharmaceuticals"**. Our Trust in association with IPA, Tamilnadu Branch celebrated Pharmacy week valedictory function in Chennai in the month of November 2011. His Excellency, Honorable Governor of Tamilnadu was the Chief Guest of the function. Our Trust instituted M. Pharm scholarship awards and the same was given to various students during the Pharmacy Week Celebration.

In this issue, we are covering the article written by Mr. C. Venkatesan, Head of Quality Assurance, Edict Pharmaceuticals on the subject of **"Facing USFDA Audit – Current Perspective"**. This article will be much useful to all our Pharma Companies for any audit by the foreign country officials for export of drugs and pharmaceuticals.

This issue also contains the extract of essay competition on the subject of **"I am a Pharmacist: Why?"** This article is written by Ms. Divyasree Medikonda, Sri Ramachandra University, Chennai, the first prize winner of the competition.

We are also covering the draft notification issued by the Ministry of Health and Family welfare on **"Payment of Compensation"** to the volunteers participated in the drug clinical trial in case of adverse reactions or death during the trial.

We are also covering some of the important Parliament question and answers pertaining to Pharmaceutical subject which will be useful for the Pharma Professionals.

In order to enrich the knowledge, important professional information / articles appeared in the important newspapers / journals are reproduced in this newsletter.

We sincerely request all our news readers to suggest for the improvement of the newsletter in future.

With best regards
Mr. R. Narayanaswamy

ARTICLES

FACING USFDA AUDIT - CURRENT PERSPECTIVE

By Mr. C.Venkatesan

Head of Quality Assurance, Edict Pharmaceuticals Pvt. Ltd

AGENDA

- FDA Expectation
- FDA Inspection Tactics
- Preparing for the Inspection
- Inspection Formalities
- Do's and Don'ts
- Plant Tour
- Close-Out Meeting

FDA Expects Pharma Industry to

- Know and Comply to cGMP Regulations
- Knows its products and processes
- Communicate problems to its Quality Unit
- Submit authentic samples
- Use appropriate test methods
- Use scientific data to justify its processes and actions
- Have a system for conducting failure investigations
- Make consumer protection their NUMBER ONE GOAL.

FDA INSPECTION TACTICS

- Formal Approach
- Pragmatic Approach
- Focused Approach
- Random, Unfocussed Approach
- Documentation Approach

Formal Approach

- Product Flow
- Organized and Step-wise assessment of Operations
- Results in a more general overview of multiple areas
- In-depth focus on random or preferred areas.

Pragmatic Approach

- Quality Assurance
- Calibration
- Maintenance

Pragmatic Approach (Contd..)

- Change Control
- Deviations handling
- Customer Complaints handling
- Training
- Recalls *etc…*

Focused Approach

- Investigator focuses on a specific area or product
- Detailed time consuming, in-depth coverage of a particular area or product.
- Review or inspection of a particular product or system until the deficiency is found and investigated.

Random, Unfocussed Approach

- The typical "fishing expedition"
- Unorganized inspectional coverage
- Many requests unrelated to one another
- Inspector looking for weaknesses in operations/systems

Documentation Approach

- Constant requests for copies of documents
- Requests for Documents to support all responses/statements.
- Focuses more on written words rather than on Product or Process.
- Also known as "Conference Room" approach to compliance auditing.

Preparing for the Inspection

- Write/Review your SOP for handling and managing an FDA Inspection
  - Detail the responsibilities for security personnel and receptionist's
  - Ensure prompt response and greeting of FDA investigators
  - Priority order of authorized persons to contact and accept the FDA-482 - Notice of Inspection
  - Ensure that backup personnel are in place and are trained
  - Departments/Personnel required to be notified of the FDA inspection
- **SOP for handling and managing an FDA Inspection**
  - State the type of records that should not be provided to the FDA investigator without prior authorization, and list who must authorize
  - List and map areas within the plant that are restricted to FDA

Preparing for the Inspection(Contd..)

- Detail the policies for signing FDA forms (who, what, under what circumstances)
- State policies and procedures for providing copies of records to the FDA
- Organize your inspection teams
  - Escort
  - Fronters /SME
  - Scriber (s)
  - Runner(s)
  - Backroom staff
  - Backups

Preparing for the Inspection(Contd..)

- *The Escort (Key Personnel accompanying inspector)*
- Traits of an Effective Escort
  - Must represent the Quality Operations department
  - Should be familiar with processes, people, and products
  - Must be diplomatic and a good communicator
  - Must have good organization skill
  - Should know to develop rapport with insp
- ***Fronters (Subject Matter Experts)***
  - Must understand their processes and procedures
  - Must understand that their comments must be limited to their areas of expertise/responsibility
  - Must listen in the ratio of 2 ears to 1 mouth

Preparing for the Inspection(Contd..)

- Must address only those questions asked (do not volunteer)
- Must need to know when to defer answers to other persons (line workers, etc.)

- ***Scribes***
  - Must be able to focus on a conversation for lengthy periods of time
  - Ability to capture concise details at speed
  - Should not become involved in conversations or emotional situations
- ***Runners***
  - Must be enough runners available to ensure full-time conference room coverage
  - Must have enough runners available to cover all investigators
  - Must be able to understand brief verbal instructions from Escort

- **Back Room Staff**
  - Must be able to work under pressure in a TEAM environment
  - Must be able to organize requests in order of receipt
  - Must have a high degree or orderliness and organization
  - Reviews any documents that will be sent to Aud
- **Senior Management**
  - Should be present at both opening and close-out meeting
  - Must extend trust and moral support the site inspection team
  - Should be available in the event a “serious” issue arises of if corporate policy is challenged by investigators
  - Closing remarks on site‘s commitment to quality and regulatory compliance is welcome

- Receptionist
- Security personnel
- The plant FDA team (facilitators, scribes, runners, backroom)
- Department managers and supervisors (cascade down to floor personnel)

- **Prepare an Opening Presentation, Including:**
- Site diagram, Organograms , Safety information, List of FDA-related products
- Review Your Previous EIRs and FDA-483s and your responses and follow-up on your commitments
- Company compliance profile
- Examine any previous observations which are yet closed out and ensure you have adequate explanation/ justification for the same

Miscellaneous Logistics-

- Travel Arrangements
  - Confirm method of transportation to and from airport, daily local transportation
- Conference Room Arrangements

An Audit Room

- Away from GMP areas, Telephone available, but not for common use, Have refreshments available
- Empty room with no distractions from operational activities
- A Staging “War” Room
- Where documents will be set-up and processing of inspector request will take place.

Handling the FDA Inspection Formalities

- FDA Inspection Room
  - Bring only appropriate personnel and records to the FDA investigator
  - Do not have unnecessary personnel or “observers“ in the inspection center
  - Be aware of the path to the inspection room or rooms
  - Avoid extensive discussions, document review, and phone conversations in the investigator‘s presence
  - Try to maintain a professional, yet non-stressful, environment
- Upon entering areas to be inspected:
  - Introduce Investigator to the Responsible Individuals in each area
  - Let the area leader answer the investigator‘s questions.

Handling the FDA Inspection Formalities (Contd...)

- ❖ Escort should remain with the investigator and monitor the conversation, but stay in the background, if possible.
- ❖ Remember, the Investigator may question employees
- ❖ Do Not Tell Investigator That He / She Cannot Question Employees

➢ Supervisors should assist when employee has difficulty in responding to questions by:

- ❖ Answering for the employee in some cases
- ❖ Re-phrasing questions
- ❖ Referring to SOPs
- ❖ Provide Flexibility to Maintain Good Relationship
- ❖ Know what you are or are not prepared to offer!

- ❖ Eg Photography , Internal audit report
- ❖ Offer privacy where appropriate
- ❖ Show trust and courtesy
- ❖ Request a brief summary at the end of each day.
- ❖ Take notes of information recorded by Inspectors and be prepared for follow-up questions

➢ ***Do's and Don'ts***

- ❖ OUR MISSION
- ❖ ---------- NOT TO:
  - ❖ Mislead the FDA investigator
  - ❖ Provide false information
  - ❖ ---------- TO:
  - ❖ Minimize confusion
  - ❖ Maintain the inspection focus
  - ❖ Facilitate the inspection process

Basic Inspection Behaviors

➢ **Negative actions**

- ❖ **DO NOT** be nervous
- ❖ **DO NOT** lie to the investigator
- ❖ **DO NOT** get over - involved with the inspection or become agitated
- ❖ **DO NOT** argue with the investigator
- ❖ **DO NOT** volunteer information… "would you like to see……," "do you need to speak to …..," "would you like to review…" etc..

➢ **Positive Actions**

- ❖ Act professionally, Provide courteous responses
- ❖ Show an interest in recommendations and comments
- ❖ Respond promptly to requests

Basic Inspection Behaviors(Contd..)

- ❖ Demonstrate your professionalism, your understanding of the regulations and your appreciation for the advise and requests of the inspector.
- ❖ You can disagree, you can discuss, and you can question: but maintain courteous and professional demeanor.

➢ **Answering Questions**

- ❖ Make Sure You Understand The Question
- ❖ It Is OK To Say That You must refer to official documentation in order to answer the question (guidelines, SOP's etc.)
- ❖ Do not provide an unsubstantiated (baseless) opinion
- ❖ Do Not Answer questions outside of your area of expertise – let the area expert answer.
- ❖ **Phrases to Avoid:**
  - ❖ I think…I suppose…I guess…
  - ❖ Normally…Usually…Generally….

Phrases to Avoid: (Contd..)

- ❖ To be honest… (as opposed to being dishonest?)
- ❖ Sometimes…Occasionally…Mostly...
- ❖ But we have always done it this way….
- ❖ But everybody in the industry does it this way….
- ❖ It's too expensive……
- ❖ *Remember*– There is no such thing as 'off the record", everything you say is for the record(even during lunch-times and breaks)…

➢ ***Reviewing Records With The Investigator***

- ❖ Do Not Point Out any Errors that you notice during the review
- ❖ Do Not Comment on the Quality of the Data you are reviewing
- ❖ Do Not Comment on Plans to Improve Record Keeping Practices – the investigator is not interested in "tomorrow"
- ❖ Do Not Correct record Errors During the Review

Did Someone Give The WRONG Answer?

➢ **Erroneous Responses To Investigator**

- ❖ Politely correct another person's response (be careful!)
- ❖ Do not argue in the investigator's presence
- ❖ Notify an inspection team member of the correct answer

The Plant Tour

First Impressions –"Remember No Second Chance"

- The inspector's goal is to gain an initial understanding of
  - The Flow of operations (material and personnel) single run through or criss cross
  - Personnel Practices
  - Facilities, Equipment and systems
- The inspector may be back for an extended examination of processes or equipment later - don't let your guard down!
- It is difficult to "live down" a bad first impression, and it puts you on the defensive. A bad second impression indicates that the initial good impression was just a show.
- **Storage Practices**
  - **Storage against wall or on floor - *not a good practice***
  - **Mixed storage of lots on a pallet -*not a good practice***

The Plant Tour(Contd..)

- Inadequate segregation/isolation of rejects, toxics, etc.
- Inadequate identification of containers and materials
- Suitable environment (temp. Humidity) , Housekeeping!

- **Sampling areas for incoming goods**
  - Environment
  - Gowning
  - Equipment used, Cleaning log book
- **Labeling and Identification**
  - Improper or incorrect labeling
  - Mislabeling of released or quarantined materials
  - Lack of identity or status labeling
  - Unlabeled containers

The Plant Tour(Contd..)

- Retest or expiration dating, "out of date lots"
- Ensure consistency

- If your labeling is electronic (barcode and SAP)
  - Is it validated?

- **Manufacturing Areas**
  - Proper cleaning
  - Contamination control
    - Dust collection
    - Pressure differentials
    - Multiple simultaneous operations
    - Correct Gowning and Regowning
    - Facility Operating Integrity and Discipline

The Plant Tour(Contd..)

- Are doors to mfg. rooms closed? Are interlocks honored?
- Are gowning standards observed?
- Are walls, extract grills, out of reach places, clean?

- **Process and Equipment Identification and Calibration**
  - Equipment and lines are identified
  - Product name is shown
  - Lot number is displayed
  - Status or phase of operation
  - Equipment logs - what is your system of recording equipment/room data, and is it logical & chronological?
  - Calibration stickers, records (expired calibrations??)
  - Maintenance records

- **Housekeeping**
  - Potentials for contamination or mix-up
  - Storage and control of cleaning materials
  - Parts lying around on floors, inconspicuous areas
- **Cleaning and Sanitization**
  - Prompt and thorough cleaning
  - Cleaning validation completed?
  - Stand/hold times before cleaning, after cleaning
  - Visual examination for residues, double checks, documented?
  - Material protection during use, storage or during break periods.

The Plant Tour (Contd..)

- **QC (Chemical, Micro) Laboratories – FDAs "HOT SPOT"**
  - Congestion and Housekeeping (open this and see what we find)
  - Labelling, labelling, labelling (reagents, reference solutions, standards, solvents, phases, equipment, samples, media)
  - Logbooks (reagents, media prep, equipment)
  - Raw data recording – legible, errors explained correctly?
  - Methods and specifications readily available
  - Stability storage area controlled?
  - Be prepared, the inspector may want to watch a person perform a test!!!

The Plant Tour (Contd..)

- **QC (Chemical, Micro) Laboratories – FDAs "HOT SPOT"**
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Documentation Review

- Batch Records and Analytical records
- SOPs
- Annual product reviews
- Validation records
- Stability program and data
- Complaints
- Maintenance and calibration
- Deviations
- Change control
- Training Documentations

CLOSE OUT MEETING

- *The Final Day*
- Establish a time for the close-out with the Investigators
- Reserve a conference room with projector, Laptop, and working!
- Determine in advance the list of attendees (inform investigators of numbers)
- Place investigators in practical location near equipment
- Provide refreshments for investigators
- Provide name placards for all attendees (name and position)
- Ensure representative upper management attendance
- Do not argue with the investigators at the close-out meeting!!
- As always be courteous.

CLOSE OUT MEETING(Contd..)

The Final Day

- Closing remarks by the main host and final word from the site manager or representative of upper management
  - Remarks should be polite and relative benign:
    - We thank you for sharing your expertise with us…
    - We will respond in a timely manner…
    - Our intention is to be fully compliant with regulations…
    - Our company strives to provide safe and effective products…
- **CAUTION -** The investigator will remember any promises that you make during the close-out. LIVE UP to your statements!

CLOSE OUT MEETING(Contd..)

Remember

- Be careful with verbal commitments - avoid "heat of moment" commitments
- Any Verbal Responses can be Included as Part of the EIR
- Negative and Sarcastic Responses are may likely be Discussed in Detail in the EIR
- Ensure that you meet all of your committments - communicate
- ALWAYS act professionally - Earn and maintain the inspectors' trust and respect

I AM A PHARMACIST…..WHY?

By Ms. Divyasree Medikonda – Final Year B. Pharm

Sri Ramachandra University, Chennai.

Lots of blood bleeding waste, untolerable pain, and cantankerous diseases brought a need for a revolutionary professional army called PHARMACY. And I am one among that army.

I am a pharmacist if I complete my course in a given period of time.In this case I am pharmacist only academically. I am a pharmacist professionally when my work is a saga of endeavour, success, hard work, outrageous invention and calculated risk taking and of public acceptance.

As a health care professional, I am supposed to be highly regulated because; slightest misstep in.

I should question myself "what is legal" which can be addressed by answering the question "what is best for the patient?"This knowledge is a must.

MEDICINES are unique as the people who discover them and the best medicines are those in which the ending is a successful treatment. I being a pharmacist heart fully accept this feel this and expect this from all my efforts.

I just want all the dreadful diseases SPOTDEAD through the army I send against them as a COMBINATION OF DRUGS.I want the cure for all the diseases to be OMNIPRESENT.

I want to go an inch wide and a mile deep and lead the study in a focussed approach. As I am in the last stage of my professional study I am going to kick start my PROFESSIONAL CARRIER.I don't want the ideas to be ideas for my life but putting them into practice and see them bear fruits.

As a pharmacist I want to devote an extraordinary amount of time to research, discuss, perform and produce fantastic results and continuously polish what I have in my hand THE FINAL PRODUCT.

I just want to be a PARADIGM of a PHARMACIST.

I want to use all the PARAPHENERNALIA related to my profession and let the result be successful.

As far as business is concerned in my mind future belongs to those pharmacists and those companies who are able to quickly focus their activities, adapt to rapidly changing markets, capitalize on Chaos and provide superior customer satisfaction.

I want to play different roles regarding my profession to be really successful.

I WANT TO BE A CREATOR:

To create revolutionary products and services by analysing how to approach the problems at hand.

I WANT TO BE AKING:

Take charge, make tough, insightful and strategic decisions to break down the barriers that prevent product adoption and avoid "DEATH MAGNETS"

I WANT TO BE A SLAVE:

To get ready for hard work and lots of it to go from revolutionary to visionary ,I need to eat like a bird eat relentlessly absorbing knowledge about my industry ,patients i.e. customers and competition and poop like an elephant spreading the large amount of information and knowledge I have gained.

I WANT TO BE AN INVENTOR:

To turn my dreams into my reality, my reality into products and my products into in to "DISEASE WEAPONS".I want to create a masterful positioning so that the entire force will be able to act on the opponent i.e. DISEASE without sustaining losses.

When I say that I am a pharmacist it does not mean that I only work for cure of diseases. A pharmacist is also related to different fields.

When I deal with cosmetics I should be a pharmacist struggling for beauty, i.e THE PHARMACIST FOR BEAUTY.

When I deal with disinfectants I am a pharmacist struggling for cleanliness, i.e THE PHARMACIST FOR CLEANLINESS.

When I deal with contraceptives I am a pharmacist struggling for threat less and harmless pleasure, i.e PHARMACIST FOR PLEASURE.

When I deal with the medicines I should place myself in the place of a PATIENT struggling for cure, i.e PHARMACIST FOR PATIENT.

PHARMACY is not just a position or profession .It is a PROCESS. And responsibility of those in the profession is to see that the process of PHARMACY occurs.

I always bow my head to PHARMACY LAW.

I DID THIS WORK BECAUSE I REALLY REALLY RESPECT AND ADMIRE MY PROFESSION.

NOTE: The above article is an extract of the Essay competition on the subject of **"I am a Pharmacist…. Why?"** which was awarded First Prize by TNPSWT.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 18th November, 2011

G.S.R. 821(E). - The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

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

[F.No.X-11014/2/2011-DFQC]
ARUN K. PANDA, Jt. Secy.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (3rd Amendment) Rules, 2011.
   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules),-
   (1) in the said rules, after rule 122DAA, the following rule shall be inserted, namely:-
   "122-DAB, - Compensation in case injury or death during the clinical trial.-
   (1) In the case of permanent injury occurring to the clinical trial subject as a result of his / her participation in the clinical trial, he / she shall be entitled for coverage of medical treatment, and financial compensation, as per recommendations of the Ethics Committee.

   (2) In the case of death of the subject as a result of his / her participation in the clinical trial, his / her legal heirs shall be entitled for financial compensation, subject to confirmation of the Ethics Committee. The financial compensation shall be over and above any expenses incurred on the treatment of the subject.

   (3) The medical treatment as well as financial compensation in the case of injury to the subject or his death shall be borne by the sponsor of the clinical trial. In the case of foreign sponsor, he shall appoint a local representative or a Clinical Research Organization (CRO) to fulfill the appropriate local responsibilities as governed by the Indian regulations and he shall also enter into an agreement with his local representative that the expenses for the medical treatment as well as compensation in the case of injury or death of trail subjects shall be borne by him.

(4) The subject shall be entitled for coverage of medical treatment and financial compensation in the cases of injury of death occurring due to the following reasons:
   (a) adverse effects of Investigational product(s)
   (b) departure from approved protocol, scientific misconduct or negligence by the Investigator or sponsor or local representative in the case of foreign sponsor or Clinical Research Organization.
   (c) failure of an Investigational Product to provide intended therapeutic effect.
   (d) administration of placebo providing no therapeutic benefits.
   (e) adverse effects due to concomitant medication administered as per approved protocol.
   (f) compensation for injury to a child in-utero because of the participation of parent in Clinical Trial.

(5) The sponsor, whether a pharmaceutical company or an institution shall undertake before the clinical trial begins, to provide compensation in case of injury or death for which subjects are entitled to compensation.

(6) The quantum of minimum compensation for the trial related injury of death shall be specified in the Informed Consent Documents. The sponsor may provide insurance coverage for any unforeseen injury wherever possible.

(7) In case the sponsor, fails to provide compensation to the trial subject for clinical trial related injuries or compensation to the legal heir(s) in case of death, the Licensing Authority may after giving an opportunity to show cause why such an order should and cancel the clinical trial or restrict sponsor / Clinical Research Organization / local representative in the case of foreign sponsor to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

Explanation:- For the purpose of this rule a clinical research organization (CRO) is an individual or an organization (commercial, academic or other) to which the sponsor may transfer or delegate some or all of the tasks, duties and / or obligations regarding a Clinical trial, provided that all such contractual transfers or obligations are defined in writing."

(2) in the said rules, in Schedule Y, in para **2. CLINICAL TRIAL,**

(a) in sub para **'(2) Responsibilities of Sponsor:'** after clause (iv), the following shall be inserted namely:-

"(v) in case of clinical trial related injury or death, the sponsor whether a pharmaceutical company, an Institution, a Clinical Research Organization or local representative in the case of foreign sponsor, shall make payment for medical treatment of the subject for injury and also provide compensation for the injury or death in the manner as prescibed in Appendix XII.

(vi) the sponsor whether a pharmaceutical company, an Institution, a Clinical Research Organization or local representative in the case of foreign sponsor who has obtained permission for conduct of clinical trial shall submit details of compensation provided or paid for such injury or death, to the Licensing Authority within 90 days of the report of the Serious Adverse Event."

(4) in sub para **'(3)** ***Responsibilities of the Investigator(s)'***:

(i) the existing clause shall be numbered as clause (I),

(ii) after the so numbered clause (i) the following clauses shall be inserted, namely;

"(ii) The investigator will provide information to the clinical trials subject through Informed Consent process as provided in appendix V about the essential elements of the clinical trial and the subject's rights to claim compensation in case of trial related injuries or death. He will also inform the subject or his / her legal heirs of their rights to contact the sponsor / Clinical Research Organization / local representative in the case of foreign sponsor of the trial and Ethics Committee for the purpose of making claims in the case of trial related injury or death.

(iii) In case of clinical trial related injury, the investigator shall request the Ethics Committee to review and make recommendations for the payment for medical treatment as well as compensation for the trial related injury or death of the subject."

(c) in clause (5) under the heading 'responsibilities of the Ethics Committee' after sub-clause (iii), the following sub-clauses shall be inserted, namely:-

(iv) In the event of a trial related injury or death, the Ethics Committee shall review the Serious Adverse Event and recommend the details of compensation to be provided by the sponsor / CRO / local representative in case of foreign sponsor.

(d) in APPENDIX V,

(i) under serial number 1, in sub serial number 1.1, the entries at number 9 shall be substituted as under, namely:

"9. Statement describing the compensations and treatment as under:

(a) In the event of a trial related injury or death, the sponsor or Clinical Research Organization or local representative in the case of foreign sponsor who has obtained who has obtained permission from the licensing authority for conduct of the clinical trial in India shall provide complete medical care and pay compensation for injury or death.

(b) At serial number 2, after the line "Subject's Initials..... Subject's Name....." the following lines shall be inserted, namely;

(ii) At serial number 2, after the line "Subject's Initials ..... Subject's Name....." the following lines shall be inserted, namely;

"Address of the Subject.....

Occupation and qualification of the Subject.....

Annual Income of the Subject....."

(iii) After the words, " name of the witness.....", the following shall be inserted, namely;

"(Copies of the Patient Information Sheet and duly filled Informed Consent Form Shall be handed over to the subject or his / her attendant also.)"

(e) After APPENDIX XI, the following shall be inserted, namely;-

"APPENDIX XII"

Compensation for Clinical Trial Subjects for Clinical Trial Related injury or death

(1) Research subject enrolled for a clinical trial who suffers a permanent injury as a result of his participation in the clinical trial is entitled for medical treatment and financial compensation. In case of death, the legal heirs of the subject are entitled for financial or material compensation. The financial or the material compensation shall be provided by the sponsor as per recommendation of Ethics Committee.

(2) In the event of an injury or death occurring during the trial, the sponsor or his representative shall prove before the Ethics Committee that the injury or death is not on account of the clinical trial within 30 days of receiving the report of injury or death from the investigator; failing which sponsor shall be liable to provide the compensation within 60 days as decided by the Ethics Committee.

(3) The compensation for clinical trial related injury or death could be in the form of:-
(a) payment for medical / surgical management of case of trial related injuries.
(b) compensation for trial related injuries leading to temporary or permanent disabilities.
(c) compensation to legal heir of the trial subject in case of death.
(d) compensation to a child injured in-utero through the participation of parent in Clinical Trial.

(4) The sponsor, whether a pharmaceutical company, an Institution, a Clinical Research Organization or local representative in the case of foreign sponsor, shall provide financial compensation if the injury or death has occurred because of any of the following reason.
(a) adverse effects of Investigational product(s) (Ips).
(b) any clinical trial procedures involved in the study.
(c) departure from approved protocol, scientific misconduct or negligence by the Investigator / Sponsor / CRO etc.
(d) failure of an Investigational Product to provide intended therapeutic effect.
(e) administration of placebo providing no therapeutic benefits.
(f) adverse effects due to concomitant medication administered as per the approved protocol.

(4) Procedure for payment of financial compensation.
(1) In the case of clinical trial related injury the trial subject, and in case of death, his legal heir may make claims, through the investigator who had enrolled the subjects for the clinical trial, to the sponsor or Clinical Research Organization or local representative in the case of foreign sponsor, who has obtained permission from the licensing authority for conducting the clinical trial in India.
(2) In case the claim has been made directly to the sponsor, Clinical Research Organization, local representative of foreign sponsor, he shall take up the matter with the investigator for authenticating the claims made as per recommendations of the Ethics Committee.
(3) The quatum of compensation shall be decided by the respective Ethics Committee in their meeting within the thirty days of the reference made to the Ethics Committee.
(4) In the cases, where no formal claims have been made by the subject, the concerned Ethics Committee shall review the Serious Adverse Event and recommend the compensation to be provided.
(5) Investigator will forward the recommendation of Ethics Committee to the sponsor / CRO or local

representative as the case may be for providing compensation.(6) Claims made by the subject shall be settled within 90 days.

(7) In case there is a dispute or difference between the involved parties (trial subject / trial subjects legal heir in case of death and sponsor / CRO, local representative in case of Foreign Sponsor, investigator) regarding amount of compensation etc. an appeal may be made to the Ethics Committee for review and re-consideration.

(8) The decision of Ethics Committee after the review shall be final.

(9) In case the research subjects or the legal heirs in case of death, are not satisfied with the decision of the Ethics Committee, they shall retain the right to seek legal remedy through the Courts.

[F.No.X. 11014/6/2011-DFQC]
ARUN K PANDA, Jt. Secy.

Foot Note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1), dated 21st December, 1945 and last amended vide notification number G.S.R. 101(E), dated the 18-2-2011.

Note:

The above notification is a draft issued by ministry of Health and Family Welfare on 18th Nov.2011.
The salient features of the notification are as follows,

1. This notification prescribes compensation for the injury or death during clinical trials.
2. The Ethics committee has to recommend the quantum of compensation as well as coverage of medical treatment.
3. The Sponsors has to provide insurance coverage for all the volunteers.
4. Drugs Controller India can take action against the sponsors who failed to provide compensation.

Editorial Policy and Disclaimer

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

INFORMATION

M. PHARM SCHOLARSHIP 2011 - 2012

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

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

This was the 14th year of these awards. We received **268 applications** from seven different branches of Pharmacy **from 20 Colleges.** All 268 synopses were sent to **Dr. S. N. Umathe**, Head – Department of Pharmaceutical Sciences, Nagpur University and his team for evaluation. Based on their best marks, **21** students have been selected for award for scholarship as per the following details:

First Rank	---	Rs. 8,000/- each for 6 candidates.
Second Rank	---	Rs. 7,000/- each for 6 candidates
Third Rank	---	Rs. 6,000/- each for 9 candidates

SUBJECT-WISE BREAK-UP

Subject		Applications	First	Second	Third
Pharmaceutics	:	61	1	1	2
Pharmaceutical Chemistry	:	46	1	1	1
Pharmaceutical Analysis	:	36	1	1	1
Pharmacology	:	38	1	1	1
Pharmacognosy	:	39	1	1	2
Pharmacy Practice	:	46	1	1	1
Biotechnology	:	02	0	0	1
TOTAL	**:**	**268**	**6**	**6**	**9**

COLLEGE-WISE BREAK-UP

Name of the college	:	Awards
1. J. S. S. College of Pharmacy, Ooty	:	10
2. SRIPMS, Coimbatore	:	3
3. S. R. M. College of Pharmacy, Kattankolathur	:	*
4. Ultra College of Pharmacy, Madurai	:	*

5. Periyar College of Pharmacy, Trichy	:	1
6. K. M. C. H. College of Pharmacy, Coimbatore	:	*
7. C. L. Baid Metha College of Pharmacy, Chennai	:	1
8. Padmavathi College of Pharmacy, Dharmapuri	:	*
9. P. S. G. College of Pharmacy, Coimbatore	:	*
10. Vel's College of Pharmacy, Chennai	:	*
11. Adiparashakthi College of Pharmacy, Melmaruvathur	:	1
12. J. K. K. Munirajah College of Pharmacy, Komarapalayam	:	*
13. Madras Medical College, Chennai	:	1
14. Madurai Medical College, Madurai	:	3
15. K. M. College of Pharmacy, Madurai	:	1
16. J. K. K. Natarajah College of Pharmacy, Komarapalayam	:	*
17. R. V. S. College of Pharmacy, Coimbatore	:	*
18. Arulmighu Kalasalingam College of Pharmacy, Srivilliputhur	:	*
19. Sri Ramachandra College of Pharmacy, Chennai	:	*
20. A. J. College of Pharmacy, Chennai	:	*
TOTAL	**:**	**21**

RESULT

PHARMACEUTICS

Rank	Name	Institute	Amount
First	Ms. S. Nancya	Periyar College of Pharmaceutical Sciences, Trichy	Rs. 8,000/-
Second	Mr. A. Sampath	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 7,000/-
Third	Mr. Prashant Kumar Hingarh	JSS College of Pharmacy, Ooty	Rs. 6,000/-
Third	Ms. A. Gokila	Madurai Medical College, Madurai	Rs. 6,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institute	Amount
First	Mr. N. Irfan	C.L.Baid Metha College of Pharmacy, Chennai	Rs. 8,000/-
Second	Ms. Swati Yadav	JSS College of Pharmacy, Ooty	Rs. 7,000/-
Third	Ms. R. Rajeswari	SRIPMS, Coimbatore	Rs. 6,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institute	Amount
First	Ms. B. Gouthami	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. J. Krishna Kiran Gupta.	SRIPMS, Coimbatore	Rs. 7,000/-
Third	Ms. Geetha Talagalla	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARMACOLOGY

Rank	Name	Institute	Amount
First	Mr. Shashank. M	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. Ankit Sen.	JSS College of Pharmacy, Ooty	Rs. 7,000/-
Third	Ms. R. T. D. Isravanya	Madras Medical College	Rs. 6,000/-

PHARMACOGNOSY

Rank	Name	Institute	Amount
First	Mr. Ismail. M	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Ms. S.Padma Thanga Parameswari	Madurai Medical College	Rs. 7,000/-
Third	Ms. Seema Talreja	JSS College of Pharmacy, Ooty	Rs. 6,000/-
Third	Ms. S. Dhanalakshmi	Madurai Medical College	Rs. 6,000/-

PHARMACY PRACTICE

Rank	Name	Institute	Amount
First	Mr. Ramesh. S	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Mr. N. Kumaran	K. M. College of Pharmacy, Madurai	Rs. 7,000/-
Third	Mr. T. Vigneswaran	SRIPMS, Coimbatore	Rs. 6,000/-

BIOTECHNOLOGY

Rank	Name	Institute	Amount
Third	Ms. Monica Mishra	JSS College of Pharmacy, Ooty	Rs. 6,000/-

M. Pharm Scholarship 2011-2012 awarded by TNPSWT

Profile of 1st Rank Projects

PHARMACEUTICS

Name: Ms. S. Nancya

Project Title: Development and Evaluation of Microemulsion for Transdermal Delivery of Lornoxicam

College: Periyar College of Pharmaceutical Sciences, Trichy.

Guide's Name:
Mrs. R. Lathaeswari M.Pharm., (Ph.D).

PHARMACEUTICAL CHEMISTRY

Name: Mr. N. Irfan

Project Title: Design, Synthesis, Insillico Studies, Characterization And Biological Evaluation of Hybrid Isoniazid Derivative

College: C. L. Baid Metha College of Pharmacy, Chennai

Guide's Name: Prof. N. Ramesh Kumar

PHARMACEUTICAL ANALYSIS

Name: Ms. B. Gouthami

Project Title: In- vitro, In-vivo Pharmacokinetic Interaction studies on Anti Depressant Drugs When co- administered with caffeinated beverages.

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name: Prof. N. Krishnaveni

PHARMACOGNOSY

Name: Mr. Ismail. M

Project Title: "Development of Pharmacokinetic profile for Gymnema sylvestre extract and its hydrolysed fraction using gymnemagenin as biomarker".

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name: Dr. B. Duraiswamy

PHARMACY PRACTICE

Name: Mr. Ramesh. S

Project Title: Effect of CYP2C19 Genetic Polymorphism on the Pharmacokinetics of Imipramine in South Indian Population

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name: Mr. K.P. Arun

PHARMACOLOGY

Name: Mr. Shashank. M

Project Title: Inhibition of Matrix Metalloproteinases and Anti-Angiogenesis in DMHInduced Colon Cancer In the Presence Of Dietary Supplements and Chemotherapy: Mechanism And Problems Based Approach.

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name: Dr. M .N. Satish Kumar

EVENTS

NATIONAL PHARMACY WEEK CELEBRATION

Indian Pharmaceutical Association, TamilNadu Branch

Governor, K. Rosaiah presenting Best Pharmacist award to S. Manivannan, Deputy Drug Controller, CDSCO, at the National Pharmacy Week celebrations in Chennai.

Governor K. Rosaiah on Saturday underlined the need for looking at the pharmaceutical sector as a strategic and flagship industry.

Speaking at the golden jubilee National Pharmacy Week celebrations here, organised by the Indian Pharmaceutical Association, Tamil Nadu Branch, the Governor said that with low cost innovation, low capital requirements, cost effective running facilities, well established manufacturing processes and R & D infrastructure, the country was destined to emerge as an alternative source for affordable medicines. "We need to look at pharmaceutical sector as a strategic and flagship industry."Mr. Rosaiah said priority areas for pharmaceutical research and development should be identified. India's expertise developing new and innovative processes for known molecules needed to be explored.

New drug development

Initiation of new drug development for diseases of relevance to Indian population was imperative. Another need was to evolve new regulatory measures to address the emerging concerns of the industry in its multifaceted dimension.
"Even though we have achieved a distinct place in globe in the pharmaceutical field, yet we have a lot to achieve."

Pharmacists should be brought into the mainstream. They should be the core member in the team towards health care, he said.
Mr. Rosaiah presented the Best Pharmacist Award to Mr. S. Manivannan, Deputy Drug Controller, Central Drug Standard Control Organisation. Speaking on this year's theme, 'Pharmacist: healthcare professional', Drug Controller, Karnataka, B. R. Jagashetty, said transparency, integrity and accountability would take pharmaceutical profession to a much higher level.The secretary of the TamilNadu Indian Pharmaceutical Association Trust, Mr. M. M. Yousuf, said the organisation was committed to updating the knowledge of pharmacists. It was active in advancing the knowledge of the public in the health care scenario.
Quality control laboratory

Plans are afoot to set up a hi-tech quality control laboratory to test the genuineness of drugs.The Association President, Mr. R. Narayanaswamy, and secretary, Mr. J. Jayaseelan, were among those who spoke.

Adhiparasakthi College of Pharmacy, Melmaruvathur

The College celebrated 50th National Pharmacy Week **(Theme – "PHARMACIST- A HEALTHCARE PROFESSIONAL")** from 20 - 27th November 2011. This was inaugurated by Dr. T. Vetrichelvan (Principal & HOD, Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy). Seven day programme included Pharmacy awareness rally in different places of Melmaruvathur and educated people about pharmacy profession, career opportunities in pharmacy and safe use of prescription medicines.

Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

The College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore had celebrated the 50th National Pharmacy Week celebrations during the third & fourth week of November 2011. As a part of the celebrations, the college has conducted a one day national seminar on **"Novel Approach of Modern Analytical Techniques in Standardization and Bio-Estimation of Herbal Drugs"** in co-ordination with the Tamil Nadu Dr. M.G.R. Medical University, Chennai on 23rd November 2011. **Dr. T. K. Ravi,** Principal, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, had been bestowed with the prestigious **"Award of Professional Excellence"** during the national pharmacy week celebrations. Eminent Speakers delivered lecture on "Quality Control of Herbal Drugs and Formulations".

NEWS

Lupin Moves Pharma Dept Against Pricing Regulator

Lupin has challenged the maximum retail price fixed by the country's drug price regulator for its anti-tuberculosis brands and a new asthma medicine. The pharma company has moved the department of pharmaceuticals, saying that the prices fixed by the National Pharmaceutical Pricing Authority (NPPA) is much below the cost sought by the company and demanded that the decision be overruled, a government official said. In September, NPPA raised the bulk drug price of rifampicin used to treat TB by 10% to Rs 4,111 per kg. This increase was based on the cost analysis of two local companies, which make the bulk drug. Lupin's MRP for brands that use rifampicin will be based on the bulk drug prices and margins for retailers and stockists.

The Mumbai-based company contested the quantum of cost raised by the regulator. In its review petition to DoP, it has sought details on how NPPA arrived at the price. Lupin said the pricemonitoring arm has not considered the cost of production submitted by it. Lupin also said that the low-cost bulk drug imported from China was even costlier than the one that is made locally, the official said. For the yet-to-be-launched asthma drug, a combination of theophylline and montelukas, NPPA fixed the retail price for a strip of 10 tablets at Rs 35.94, far less than Rs 49.10 sought by Lupin. A favourable decision for Lupin will improve its profitability as it is a global leader in the TB segment, which accounted for about 10% of its total annual sales of Rs 1,575 crore in the country.

A Lupin spokesman declined to comment citing the silent period ahead of the company's quarterly results announcement on Wednesday. NPPA fixes the retail prices of all medicines made using 74 drugs, to make medicines affordable for consumers.

Companies *unhappy with NPPA's price notification take their* appeal to the department. According to an NPPA official, the price watchdog has given its comments to the DoP. “The department has to balance the interests of the company and consumers,” he said

Source: *The Economic Times, 7th November 2011*

More Drugs to Come under Price Control

10% of Patients Would Have Died Without Govt Hosps: SC

The Centre on Thursday responded to the Supreme Court's concern over spiraling prices of essential medicines and promised to make all out efforts to put under strict price control regime all 348 drugs included in the National List of Essential Medicines (NLEM), 2011. A bench comprising Justices G. S. Singhvi and S. J. Mukhopadhaya had expressed serious concern over the shrinking list of medicines under the Drug Price Control Order (DPCO) and had asked for the Centre's response on bringing the NLEM medicines under price control regime. The government admitted that more than 300 drugs were under DPCO in the early 1980s which was subsequently reduced to 140 drugs in 1987. At present, under DPCO, 1995, the prices of only 74 bulk drugs and formulations containing any of these scheduled drugs were under price control regime, it said. Once a medicine was brought under DPCO, it could not be sold at a price higher than that fixed by the government. The ministry of health and family welfare then made a solemn promise in an affidavit, “It is the considered view of the answering respondents that to make affordable healthcare a reality, all the medicines included in the NLEM, 2011 need to be brought within the ambit of price control under the DPCO, considering the fact that the cost of medicines constitutes more than 60% of the overall cost of healthcare.” NLEM included 348 medicines which cover 489 formulations, including 16 Fixed Dose Combinations. These drugs are

considered to be adequate to meet the common contemporary health needs of the general population of the country, the ministry said. "It would be the general obligation of the health administrators to ensure abundant availability of these drugs in the country," it said.

Source: *The Times of India, 18th November 2011*

Drug Price Control Hurts R&D Potency

It is incredible how the right ambience can make all the difference between success and failure or boom and gloom. Service sectors such as advertising have creative people who can absorb all the pressure of tight deadlines and yet deliver excellent campaigns - provided their ambience offers the right stimulation. Similarly, industry arms such as R&D thrive in an atmosphere devoid of controls and constraints.

Creativity and innovation suffer with controls. The pharmaceutical industry is one such sector where the R&D section could deliver a pipeline of innovative drugs, despite legendary difficulties in making new breakthroughs. Discoveries and inventions occur at periodic intervals if researchers are given full freedom and generous budgets. The periodic supply of innovative drugs ensures new disease strains are kept in check. If the pipeline of new drugs were to dry up, a decade or more down the line, there would be fewer drugs going off-patent. This, in turn, would impact manufacture of generic drugs that come into being when innovative drugs go off-patent.

In other words, innovative drugs ultimately benefit the generics industry too. By using price control measures to cap drug prices, authorities will not just stifle innovation, but also disrupt the pipeline of innovative drugs.

That price control negatively impacts R&D expenditure, thereby curtailing the development of new medicines, is clear from the experience of developed and other developing nations that have tried this strategy at some time or the other. Take the case of the US - the legendary land of inventions and innovations.

In 1993, the possibility of price controls was officially announced at the end of the third quarter. The price control option persisted till the second quarter of 1994. By early 1995, its effect was all too apparent. Between 1991 and 1994, both foreign and domestic companies increased their research intensity at approximately the same pace. In 1995, however, firms focused on international operations had substantially hiked their R&D spends. But companies focused on domestic operations simply did not.

In other words, domestic firms froze R&D spends simply because they were apprehensive about the possibility of price controls. One can imagine the impact in countries where price controls were actually imposed, not just threatened. France has one of the most stringent price control regimes in Europe.

It is no surprise then that innovative molecules developed in the country fell sharply after price controls were imposed. Or consider Canada. Once price controls curtailed revenues of subsidiaries, parent companies were thereafter reluctant to hike the R&D mandates of these companies. Naturally, R&D investments as a proportion of sales revenues fell sharply in Canada between 1995 and 2004. In Germany too, after price controls were imposed, pharmaceutical R&D in German pharma companies fell by 13% between 1989 and 1995. And in New Zealand, R&D spends are extremely low because of the high degree of prices controls in pharmaceuticals.

Research also reveals a significant delay in the launch of new drugs in price-control countries. Companies delay launch of drugs in price-controlled markets because nations without price caps allow them the freedom to set a better benchmark price that helps recover R&D costs within a reasonable timeframe. In price-regulated countries, the cost-recovery timelines may stretch longer and closer to the period when the drugs go off-patent.

Companies, therefore, prefer to either not launch or delay the launch in such countries. This is done to

avoid the negative spillover of a lower, regulated price, say, for instance in India, on the price of a non-regulated country such as Sri Lanka. As a result of this pricing precaution, India will either not receive the new drug or will only receive it some years later. Apart from this, research establishes that drugs discovered by companies based in nations with price controls reach fewer markets and after more delays than those originating in countries without price controls. The net result of price control is low, falling R&D spends and, consequently, a new drugs pipeline that quickly dries up. Not only does the industry suffer as a consequence, patients also suffer because death and disease rates gradually go up as the most effective drugs are no longer available. Considering the negative results in many nations over the years, it makes sense to learn from their experience and revoke price control measures at the earliest. This will ensure there is a sustained supply of new drugs, particularly to combat the spread of new disease strains and the rising threat from lifestyle as well as chronic diseases.

(The Author Mr. Vijaya Katt is professor and chairperson at the Indian Institute of Foreign Trade)

Source: *The Economic Times, 24th November 2011*

Not enough Drug Inspectors as online sales thrive

Vivek Narayanan TNN

With online pharmacies under the scanner, the shortage of drug control inspectors and the absence of a mechanism to monitor internet sales is back in focus. Across the country, there is a shortage of 3,000officers and in Tamil Nadu there are only 79officerstocover all the districts.

Drug sales have been increasing steadily in the country: In 1947, it was for .10 crore, in 1982, itwas. 1,500 crore and it currently stands at. One lakh crore. "This increases the necessity to check pharmacy sales and also ensure that qualified pharmacists are present to sell prescription drugs," said Ravi Uday Bhaskar, secretary general of All India Drugs Control Officers Confederation. Drug control officers include directors and joint directors up to the drug inspectors' level. Andhra Pradesh has 155 officers, Karnataka 130, Kerala 48 and Tamil Nadu 79. "After Kerala, Tamil Nadu is facing an acute shortage. At the national level, there are 1,500 officers. This number is inadequate considering the fact that medicine sales is increasing in the country," said Bhaskar.

The rise of online pharmacies has compounded the problem. As of now, they don't have a mechanism to check drugs sold online. "A majority of the medicines sold online are psychotropic drugs," Bhaskar said, adding drugs that increase sexual performance are also popular online.

Narcotics Control Bureau (NCB) sleuths recently arrested four pharmaceutical distributors in TN for supplying psychotropic drugs through couriers to the US, Canada and European countries. NCB had earlier arrested Alexander Vyukhin, 48, a Russian national, and C. Sankar, 48, a wholesale drug dealer, in September for the same case. The two ran an online pharmacy, which sourced drugs from the four distributors. Though there is no mechanism in placeto monitors online trading, it would soon be put in place soon. "We will alert all officers across the country and ensure that something is done to tackle the issue," said Bhaskar. "There is a need for coordinated effort among all enforcement agencies, including the Narcotics ControlBureau.

ON THE EDGE

The number of qualified professionals is inadequate considering the rise in medicine sales across the country Andhra Pradesh has about 155 drug inspectors, Karnataka has around 130 and Kerala has about 48 Drugs sales have seen exponential rise. In 1947, total sales amounted to 10 crore, in 1982, it was 1,500 crore and currently, it is close to 1 lakh crore 50% of conventional pharmacies do not have qualified pharmacists while 95% of chain pharmacies boast of qualified staff.

Source: *The Times of India, 28th November 2011*

Low-Cost Diabetes Drug Can Reduce Cancer Risk

A low-cost diabetes drug seems to beat the growth of breast cancer, especially by preventing a number of natural and man-made chemicals that promote it. James Trosko from Michigan State University and a team from South Korea's Seoul National University have thrown up evidence to show that use of Metformin for Type-2 diabetes reduces risk of cancers. "People with Type-2 diabetes are known to be at high risk for several diabetes- associated cancers such as breast, liver and pancreatic cancers," said Trosko, Paediatrics professor at Michigan's College of Human Medicine. "While Metformin reduces risk of these cancers, there is no evidence of how it worked," he said.

Source: *The Times of India, 28th November 2011*

Gene that controls sleep identified

Scientists have discovered a gene which they claim holds the key to the secret of an internal alarm clock which allows some people to get by on just four hours of sleep a night.

A team at the Ludwig Maximilians University of Munich has identified the gene, called ABCC9 that can reduce the length of time people sleep. The same gene has previously been linked to heart disease and diabetes.

The scientists have based their findings on a Europe-wide survey which saw nearly 4,000 people from seven countries fill out a questionnaire assessing their sleep habits. They then analysed their answers as well as participants' genes. The findings revealed that people who had two copies of one common variant of ABCC9 slept for "significantly shorter" periods than people with two copies of another version. Having already established that the ABCC9 gene was also present in fruit flies, the teams were able to modify it in the animal and shorten the length of time for which it slept, the 'Daily Mail' reported. Lead author of the study said: "Apparently the relationships of sleep duration with other conditions such as heart disease and diabetes can be in part explained by an underlying common molecular mechanism." PTI

Source: *The Times of India, 28th November 2011*

Govt May Ask Doctors to Prescribe Low-cost Drugs

KHOMBA SINGH NEW DELHI

The health ministry plans to make it mandatory for doctors to write name of low-cost chemical equivalents of costlier brands during prescription that can reduce cost of medicines by more than half but reduce margins of drug companies.

The health ministry plans to initially roll out the service with central government hospitals; and gradually expand it to individual states and private sector, additional secretary and director general (CGHS), Department of Health L. C. Goyal told ET. Doctors will have a database that list most branded medicines along with their chemical. So, whenever they prescribe a branded drug, they can immediately refer to its generic equivalent and write it along with the prescription. The health ministry has identified couple of firms who have already developed similar database for generic equivalents. "We are getting into it but we have to be cautious. It has to be 100% accurate because there is an issue of safety," he said. There are an estimated 90,000 drug brands sold in the country marketed by thousands of drugmakers. Most generic equivalents cost fraction of the branded ones. For example, if a consumer is prescribed Crocin, the doctor will also write the chemical name, which is Paracetamol that costs as low as one fourth of Crocin.

Since drugs cannot be advertised, companies' marketing strategy is to push their brands through doctors. This has led to a wide unethical practice of luring doctors with incentives such as gifts and sponsoring trips to prescribe their brands over others. This increases marketing expenses of companies, often passed on to consumers. The government has been concerned about this practice but has been unable to curb it. A Cipla spokesman said it will impact the business of drug firms but its impact will depend on how effectively the plan is enforced.

Source: *The Economic Times, 16th December 2011*

Undergraduate Pharmacy Courses Planned in two Government Colleges

Pharmacists told to dispense medicines only in doctor's prescriptions Chennai: It is necessary for every pharmacy to have a full-time pharmacist to ensure that drugs are dispensed correctly and that the patient is provided the best care, Health Minister V.S. Vijay said here on Friday. Speaking at a function organised by the Tamil Nadu Dr. MGR Medical University as part of the national pharmacy week celebrations, he urged pharmacists to dispense drugs only on doctor's prescriptions and to ensure safe storage of drugs.

The State government proposed to offer undergraduate pharmacy courses in the government colleges in Thanjavur and Coimbatore from the next academic year, the Minister said, pointing out that the State provided expensive drugs free of cost at its hospitals.

Currently, there are 43 colleges in the State with around 1,300 postgraduate, 2,000 undergraduate and 2,400 diploma students. The Pharmacy Council of Tamil Nadu has 63,000 members of which 18,000 are pharmacy graduates and the rest are diploma holders. Lauding Tamil Nadu's achievement in Healthcare, Governor K. Rosaiah urged pharmacists to ensure safe and quality drugs are provided to the patients."Pharmacists are expected to use their knowledge and expertise to educate the public regarding rational drug use, prevention of communicable diseases, methods of family planning and importance of good health. It is a career with a blend of science, healthcare, patient care, computer technology and business," Mr. Rosaiahsaid. Girija Vaidyanathan, principal secretary, Health, who lauded the pharmacists said they were not traders but a healthcare profession. "Pharmacists are the face of the public health system. In primary health care centres pharmacists play a key role in the success of the National Rural Health Care Mission," she said. Mr. Rosaiah and Dr. Vijay presented awards to doctors for their achievements, for excellence in practice and for service. Awards were presented to teachers of pharmacy and practicing pharmacists from across the State on the occasion.

Source: *The Hindu, 26th November 2011*

Medicines for All

Achieving universal health coverage through an equitable system is among the key goals of India's 12th Plan. Within the overall objective of creating an entitlement-based health care system, one of the challenges is access to medicines. The High Level Expert Group instituted by the Planning Commission on Universal Health Coverage underscores serious policy distortions and inefficiencies that stand in the way of making essential medicines accessible to all. A far-sighted programme assuring free or affordable access to drugs can make a big difference.

Today household expenditure on drugs constitutes 71 per cent of all out-of-pocket spending on health. Reducing this burden requires a carefully crafted plan, the blueprint for which has been presented by the expert group chaired by Dr. K. Srinath Reddy. What it requires is greater public investment on drugs, an expanded official list of essential

medicines, effective price controls for essential drugs, and a pooled procurement system that leverages the benefits of scale to drive costs down. The substantial cost benefits of centralised procurement for the government system have been convincingly demonstrated in Tamil Nadu, encouraging Kerala to adopt the same model; Bihar, Madhya Pradesh, and Orissa are in the process of replicating it.

National Sample Survey data indicate that free drugs supplied during hospitalization declined from 31.20 per cent in 1986-87 to 8.99 per cent in 2004. The high cost of medicines from the mid-1990s resulted in out-patients not receiving drugs in one-fourth of all cases by 2004, up from 12.11 per cent in the base year. It is important therefore that the central government acts urgently on the expert group's suggestion to move to a system where essential medicines are available free of cost to everyone. It is estimated that this can be achieved through a four-fold increase in public spending on drugs. Such a programme should rely mainly on quality generic drugs produced by a revitalized public sector and compulsory licensing under the TRIPS Agreement of WTO. It is worth pointing out that in the absence of social health insurance, several patented medicines are beyond the reach of the majority of Indians. More households will come under calamitous pressure, if enhanced patent provisions forming part of bilateral agreements (such as those with the European Union and Japan) lead to higher drug prices. Rising India with its hundreds of millions of desperately poor people can ill afford to go down that path. Creating a system of standard treatment, pooled procurement, and decentralized distribution by the government, which will lead to massive savings, brooks no delay.

Source: *The Hindu, 29th December 2011*

12 M.P. Doctors Fined for Conducting Drug Trials

The Madhya Pradesh government has fined 12 doctors Rs. 5,000 each for conducting drug trials on children and mentally challenged persons, even as the Opposition Congress termed the fine an "eyewash" and a "joke" and demanded a CBI probe into the matter. Besides fining the doctors, the government issued instructions for banning new drug/clinical trials with retrospective effect from October 25, 2010 in medical colleges of the State and hospitals attached to them.

The Doctors were fined for not maintaining records of tests and treatment and failure to provide requisite details to the Chief Medical and Health Officer under the Madhya Pradesh Nursing Home and Clinical Establishment (Registration and Licence) Act.

The Congress criticised the State government for levying a meagre fine for "such a grave, inhuman crime" and accused it of selling out to multinational pharmaceutical companies.

"The lives of the poor patients who were victimised in the name of drug trials is just Rs. 5,000? We demand a CBI inquiry in the matter," said Leader of the Opposition in the Assembly Ajay Singh.

A State government communication informed that "while there was no provision in Schedule 'Y' of the Drugs and Cosmetic Rules 1945 for powers to States to monitor/regulate drug/clinical trials," instructions were issued to the Madhya Pradesh Health Commissioner and the Chief Medical and Health Officer, Indore to get registered with the Clinical Trial Registry of India under the Central Drug Controller and then seek drug trial-related information from 38 doctors of the Public Health and the Family Welfare Department.

Earlier, the Doctors refused to provide details of drug/vaccine trials to the government citing provisions of the Drug and Cosmetic Rules 1945.

The Chief Medical and Health Officer, Indore, also sought details in this connection from the president of the Nursing Home Association and the president of the Indian Medical Association, Indore.The State Government expressed its inability to conduct any detailed investigation involving the patient/subjects under trials, citing legal provisions that protect the identity of trial subjects.

Source: *The Hindu, 2nd January 2012*

Human trials for HIV vaccine Get Under Way

London: Scientists are carrying out what they claim is the first clinical trial of an injectable vaccine for HIV which causes AIDS. A team from Imperial College, Hull York Medical School, Medical Research Council Clinical Trial Unit and Infectious Disease Research Institute is evaluating whether the vaccine is safe for use in human volunteers.

The vaccine contains trimeric HIV envelope protein (gp140) which can target the virus' most virulent strain Clade C that has caused the greatest number of HIV infections around the globe, infecting half of the 34 million people with HIV. The trial, which is funded by the Welcome Trust and goes by the name MUCOVAC2, is evaluating a vaccine that contains the HIV trimeric gp140 protein CN54, representative of Clade C strains of the virus. This clade of HIV is the most prevalent type of virus in Sub-Saharan Africa and responsible for the greatest number of infections globally.

The trimeric protein represents the major target for antibodies on the viral surface. The vaccine candidate will be formulated with an adjuvant — GLA — developed to enhance immune responsiveness following intramuscular injection. GLA formulations have been previously tested clinically with promising results. The scientists have enrolled 36 healthy, HIV-negative women aged 18-45 years at St George's University of London and the HYMS Experimental Medicine Unit at York Hospital. PTI

Source: *The Times of India, 4th January 2012*

MNCS move SC Over Drug Price Control

MUMBAI: Till now, pharma companies, opposing price control, have been trying to make their voices heard in the corridors of power.

With the courts recently stepping in to bring essential medicines under a price control regime, multinational-led industry body OPPI (Organization of Pharmaceutical Producers of India) has moved the Supreme Court seeking to be heard on the drug pricing issue. OPPI through an application seeking

"impleadment" in the ongoing public interest litigation on the drug pricing issue in the Supreme Court wants to be a formal party in the case. Sources said that the OPPI filed the application to engage with the government "more actively", and wanted to ensure that its case is heard. The PIL was filed by health groups led by All India Drug Action Network, seeking essential drugs to be regulated under a price control regime in 2003. The "impleadment" application was filed on November 12, and later admitted by the court.

"The OPPI moved the Supreme Court to get impleaded as a party in the ongoing PIL because the drug pricing issue affects our industry's ability to sustainably provide medicines-both innovative and generic-to the population in India, and, hence will have an effect on public health and access to medicines, as well as the economic development of the pharma industry," OPPI president Ranjit Shahani told TOI.

At present, 74 bulk drugs and their formulations (around 1,500) are included in the existing DPCO (Drug Prices Control Order, 1995), which covers 20% of the market. Recently, the department of pharmaceuticals formulated a draft policy on all 348 essential medicines (National list of essential medicines) whoseprices would be controlled through a market-based pricing mechanism. The draft policy covers 60% of the over Rs 60,000 crore market, and will be finalized after comments from all the stakeholders have been received.

The Supreme Court had earlier expressed concern over the dwindling list of medicines under price control, and sought the government's response in bringing essential drugs under a price control regime.

Earlier this year, the ministry of health revised the NLEM totalling 348 medicines which cover 489 formulations, including 16 fixed dose combinations. These drugs are considered to be adequate to meet the common contemporary health needs of the general population of the country, the health ministry has said. "It would be the general obligation of the health administrators to ensure abundant availability of

these drugs in the country," it said in the affidavit.

The Ministry of health and family welfare had promised in an affidavit, "It is the considered view of the respondents that to make affordable healthcare a reality, all the medicines included in the NLEM, 2011 need to be brought within the ambit of price control, considering that cost of medicines constitutes over 60% of the total cost of healthcare." The Centre had tried to introduce the new policy on two earlier occasions, but without any success. In 2002, the policy was challenged in the courts while in 2006, it was revised. However, it was considered anti-industry, and later got stuck at the GoM on pharmaceutical policy level, which is where it stands today.

Source: *The Times of India, 23rd November 2011*

Protecting an Anti-Malarial Drug from Developing Resistance

It is a drug that has its roots in ancient Chinese medicine. In the fight against malaria, a disease that over 200 million people are estimated to have caught in 2010, some 655,000 of whom died of it, protecting the effectiveness of artemisinin-based drugs has become vitally important.

A number of Indian pharmaceutical companies have been among those manufacturing and marketing drugs that are likely to foster resistance to artemisinin in the malaria parasite, according to the latest World Malaria Report that was recently released.

However, India's Drugs Controller General initiated action earlier this year to stop the production and export of these drugs.

Artemisin and its derivatives have saved countless lives after the single-celled parasite, Plasmodium falciparum, that causes the most dangerous forms of the disease became resistant to the drug chloroquine. However, strains that are resistant to even artemisinin have emerged in parts of South-East Asia and could potentially spread, as has happened with earlier antimalarial drugs.

“A looming threat to malaria control is the emergence of parasites that are resistant to antimalarial medicines,” pointed out the World Health Organisation (WHO) in its 'Global Plan for Artemisinin Resistance Containment' published earlier this year. Resistance had developed to every antimalarial medicine used so far. When that happened, the burden of malaria increased. Child mortality in Africa increased, for instance, as P. falciparum strains that were resistant to chloroquine spread in the 1970s and the 1980s.

Although the problem of artemisinin resistance is currently confined to the Mekong river region, there is now “early evidence” of such resistance in Myanmar and Vietnam, warned Margaret Chan, the WHO's Director-General, in a foreword to the World Malaria Report 2011.

“Exposure of malaria parasites to suboptimal doses of artemisinin is a primary cause of the spread of resistance,” the Global Plan noted. Giving artemisinin and its derivatives alone as 'monotherapies,' instead of as a cocktail with another drug, could create opportunities for resistant forms of the parasite to arise and spread.

Although oral artemisinin-based monotherapies could be effective when taken for the full seven-day course, patients often stopped taking them after just a few days when the symptoms generally subsided. Parasites that were sensitive to the drug could get eliminated, allowing drug-resistant strains to proliferate and get transmitted to other people.

To prevent that from happening, the global health agency recommends that artemisinin be given in combination with another drug. Such artemisinin-based combination therapy (ACT) should, it says, be first-line treatment for uncomplicated malaria caused by P. falciparum. The two-drug combination reduced the chances of the parasite developing resistance. Moreover, a three-day course of a recommended ACT generally cleared the parasites from the body.

The use of ACT has grown rapidly. Globally, the number of ACT courses procured by the public sector jumped nearly seven-fold between 2005 and 2006,

and then more than doubled, reaching 181 million, in 2010, according to the World Malaria Report. The demand for these drugs was expected to reach 287 million treatments this year and touch 295 million courses in 2012.

In 2006, the WHO called for a halt to using oral artemisinin monotherapies to treat uncomplicated malaria. This was followed a year later by a resolution adopted by the World Health Assembly, the WHO's apex decision-making body, that urged its member states to "cease progressively the provision in both the public and private sectors" of such monotherapies and promote the use of ACTs.

However, according to the latest World Malaria Report, 25 countries were still allowing the marketing of these products and 28 pharmaceutical companies were making these drugs, down from 39 a year ago. "Most of the countries that still allow the marketing of monotherapies are located in the African Region, while most of the manufacturers are located in India."

Ten of the 28 manufacturers of monotherapies were in India, according to a spokesperson for the WHO Global Malaria Programme.

The WHO has called on all manufacturers to cease the marketing of monotherapies. Besides, "greater collaboration and involvement of national regulatory authorities is required to ensure complete withdrawal of oral artemisinin-based monotherapies from all countries," noted the World Malaria Report.
"Oral artemisinin monotherapy is banned in India," according to the 'Guidelines for Diagnosis and Treatment of Malaria in India' published in 2010 by the National Institute of Malaria Research in Delhi and the Union Health Ministry's National Vector Borne Disease Control Programme.

In April this year, DCGI wrote to all State Drugs Controllers requesting them to cancel licenses to manufacture oral artemisinin-based monotherapies with immediate effect. The manufacturing of such monotherapies for export should also be stopped. "We have been very encouraged by the steps that the Government of India has taken over the past year," said Robert Newman, director of the Global Malaria Programme at a press conference to mark the release of the World Malaria Report.

Source: *The Hindu, 22nd December 2011*

More Potent Ways to Design HIV Drugs Found

In perhaps the most comprehensive survey of the inner workings of HIV, an international team of scientists led by researchers at the University of California, San Francisco has mapped every apparent physical interaction the virus makes with components of the human cells it infects.

This work may reveal new ways to design future HIV/AIDS drugs.

In back-to-back papers published today (December 22) in the journal Nature, the survey reveals a pathogenic landscape in which HIV's handful of proteins makes hundreds of physical connections with human proteins and other components inside the cell.

In one paper, the team details 497 such connections, only a handful of which had been previously recognized by scientists. Disrupting these connections may interfere with HIV's lifecycle, and the existence of so many new connections suggests there may be several novel ways to target the virus.

"Have we identified new drug targets?" said Nevan Krogan, who led the research. "I believe we have." Krogan is an associate professor of Cellular and Molecular Pharmacology at UCSF.

In a companion paper, Krogan and collaborating labs investigated one such connection in detail. They discovered that an HIV protein called Vif makes a physical connection with a human protein called CBF-â, hijacking its function.

This virus requires this action to function, said Krogan, which suggests that disrupting the connection may be a viable way to design new HIV/AIDS therapies.

Unlocking the doors

The UCSF-led study has provided the most comprehensive and detailed picture to date of all the interactions HIV has with the human cells it infects,

and identifying these interactions may lead to the development of new drugs to treat the disease.

Of the 497 specific interactions between HIV and human proteins discovered in the new work, only 19 of those were previously reported.

What accounts for the discrepancy, Krogan said, is that this was the first study to look for such interactions globally and in an unbiased fashion – unlike previous studies, which had been more focused.

Interfering with this association may be a way to block the virus. Ultimately, if scientists can design compounds to do this safely and effectively, those compounds could form the basis for a new type of HIV/AIDS treatment.

Source: *The Hindu, 22nd December 2011*

Government to Prescribe Standards for Clinics, Hospitals In Four States

Khomba Singh

NEW DELHI: The government will make it mandatory for all hospitals and clinics in some small states to adhere to minimum clinical standards. The move could be extended to other states too.

This means that if a hospital provides a particular service, say, a bypass surgery, then it will have to ensure it has the minimum stipulated equipment, manpower and infrastructure.

Although the law will be limited to some states, it will be the first time that there will be a specified national law for standards of treatment that could also result in penalty for errant healthcare service providers. The health ministry plans to notify the Clinical Establishments Act 2010 by March, a senior health ministry official said. Although health is a state subject, the central government can intervene if states approach it. The centre has framed this legislation at the behest of four states - Himachal Pradesh, Sikkim, Arunachal Pradesh and Mizoram. Accordingly, the law will apply only to these states. The health ministry wants to extend it to others though it has clarified to other state health ministries that the Act is "not intrusive", but moved in public interest.

While Rajasthan has agreed to adopt the legislation, Bihar and Orissa have also indicated their willingness to do so.

Indian healthcare, projected to touch $75 billion this year, is highly fragmented and unregulated.

Source: *The Economic Times, 18th January 2012*

US to Force Drug Firms to Report Money Paid to Docs

To head off medical conflicts of interest, the Obama administration is poised to require drug companies to disclose the payments they make to doctors for research, consulting, speaking, travel and entertainment. Many researchers have found evidence that such payments can influence doctors' treatment decisions and contribute to higher costs by encouraging the use of more expensive drugs and medical devices. Consumer advocates and members of Congress say patients may benefit from the new standards, being issued by the government under the new health care law.

Officials said the disclosures increased the likelihood that doctors would make decisions in the best interests of patients, without regard to the doctors' financial interests. Large numbers of doctors receive payments from drug and device companies every year — sometimes into the hundreds of thousands or millions of dollars — in exchange for providing advice and giving lectures. The Times has found that doctors who take money from drug makers often practice medicine differently from those who do not and that they are more willing to prescribe drugs in risky and unapproved ways.

Companies will be subject to a penalty up to $10,000 for each payment they fail to report. A company that knowingly fails to report payments will be subject to a penalty up to $100,000 for each violation, up to a total of $1 million a year.

Source: *The Economic Times, 18th January 2012*

The Genetics Gamble

The Chennai couple who advertised online for sperm donations preferably from IIT students is merely skipping a few steps — and the social niceties — that go into the usual arranged-match strategy. Matrimonial columns are proof enough that Indian parents still have deep faith in genetics, even if the melting pot of urban existence is slowly diminishing caste biases. Complexion, height and weight are as important as earning potential, and a preference for 'Class I' civil servants, MBAs, chartered accountants and the like has as much to do with future prosperity as the potential IQ of their progeny, given that clearing public exams demands formidable RAM (random access memory) these days. Though there are enough instances to prove that like does not always beget like — data on how many offspring of IITians also crack the entrance exam would be illuminating — the average Indian parent's belief in DNA remains unshakeable. But lassoing a suitable boy is as difficult as the search is tedious, expensive and time-consuming, and there are simply not that many IIT-IIM graduates, IAS/IPS/Allied Services officials and CAs available — that too at an affordable price.

The next best thing, obviously, is to aim for a small stake in a blue chip if a merger is not possible; the Chennai couple have obviously realised that. For those who believe in the genetics game, the attraction is clear: it is definitely cheaper than snagging a whole IITian or what-have-you, and thinking of them as sperm banks rather than individuals expands the market exponentially. It also opens up alternative sources of funding for 'needy' IIT-IIM students. Of course, there is no telling what other traits could be inherited along with formidable IQs, but that's a risk many may be willing to take.

Source: *The Economic Times, 18th January 2012*

Novartis to Slash 2,000 Jobs in the US

Novartis is cutting nearly 2,000 jobs in the United States ahead of the patent loss of top-selling blood pressure drug Diovan as it braces for tough market conditions and a slump in sales of another key drug. Novartis is the latest in a long line of global drugmakers to cut their sales forces as the industry faces its biggest wave of patent expiries in its history.

The group will book a one-off charge of $900 million in the fourth quarter after a clinical trial showed patients taking its blood pressure pill Rasilez actually did worse, meaning sales of the treatment, previously tipped to rake in sales of more than $1 billion, are likely to plunge. The Swiss drugmaker is currently in talks with regulatory authorities on both sides of the Atlantic about whether this drug, once seen as a Diovan successor, could end up being pulled from the market, a spokesman said on Friday. "We recognize that the next two years will be challenging in the Pharmaceuticals Division and we are proactively making these changes to further focus our pipeline on the best opportunities," David Epstein, the group's pharma chief said. Novartis shares were indicated to open 1.5% lower, according to premarket data from Clariden Leu, but Helvea analyst Karl-Heinz Koch said the move would boost margins and accelerate its push into specialty care. Novartis plans to cut 1,630 jobs in its US field force and another 330 positions are expected to go as it reorganizes the headquarters of its US general medicines business. The changes are expected to take place in the second quarter of this year.

The group anticipates the restructuring measures, which will result in a charge of $160 million in the first quarter of 2012, will lead to annual savings of $450 million by 2013. Novartis' latest round of job cuts comes just months after it said it was cutting 2,000 jobs in Switzerland and the United States to keep costs under control in the face of growing price pressures.

Source: *The Economic Times, 14th January 2012*

PARLIAMENT QUESTION – ANSWERS

RAJYA SABHA

CHEMICALS AND FERTILIZERS

QUESTION NO : 3294
ANSWERED ON : 02.09.2011

STEEP RISE IN PRICES OF LIFE SAVING DRUGS.

3294 SHRI BRIJLAL KHABRI

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state :-

(a) whether Government is aware of the fact that there is a steep rise in the prices of life saving drugs in the country;

(b) if so, the details thereof;

(c) whether Government is aware that people living under BPL are succumbing to death being unable to purchase life saving medicines due to this price rise;

(d) whether Government is taking effective steps to control the prices of essential medicines; and

(e) if so, the details thereof?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b) : Under the provisions of Drugs (Prices Control) Order, 1995 (DPCO,95) the prices of 74 scheduled bulk drugs and the formulation containing any of these scheduled drugs are controlled. National Pharmaceutical Pricing Authority (NPPA) fixes or revises prices of scheduled drugs / formulations as per the provisions of the DPCO,95. No one can sell any scheduled drug / formulation at a price higher than the price fixed by NPPA / Govt. In respect of drugs not covered under the DPCO,95 i.e. non scheduled drugs, manufacturers are at liberty to fix the prices by themselves without seeking the approval of Government / NPPA. During the current financial year 2011-12 (up to 31st July, 2011), the prices of 273 scheduled medicine packs have been fixed / revised by the NPPA, out of which only in 95 cases the prices were increased which comprises 34.80% of the total cases for which prices were fixed / revised during the year. In the remaining cases, prices were either reduced or fixed for the first time or there was no change in the price. The details of fixation of price of scheduled formulation during the last two years and the current year (upto July,2011) is as under:

	2008-09		2009-10		2010-11 (up to 31st July,11)		2011-12		Since inception of NPPA (up to 31st July,11)	
	Nos.	%age	Nos.	%age	Nos.	%age	Nos.	%age	Nos.	%age
Price Increased	190	12.05	184	10.08	223	31.28	95	34.80	1627	14.37
Price Decreased	89	5.64	450	24.67	60	8.42	30	10.99	3389	29.92
Price fixed for the first time	1256	79.65	1155	63.33	371	52.03	114	41.76	5937	52.42
No change in prices	42	2.66	35	1.92	59	8.27	34	12.45	373	3.29
Total	1577	100	1824	100	713	100	273	100	11326	100

Includes Pro-rata prices fixed

(c) : No such information is centrally available.

(d) & (e): Apart from purchase of samples by the officers of NPPA from different parts of the country, complaints by individuals / NGOs and report from the State Drug Controllers are utilized to ensure compliances of the prices fixed / notified by the NPPA / Government. Price list submitted by the companies in Form V are scrutinized for the purpose. In case a company is found selling any scheduled formulation at a price higher that notified / approved by the NPPA / Government, action is taken against such companies as per the provision of DPCO,95 for recovery of the overcharged amount. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG-IMS and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum (20% before 01.04.2007) is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process. Based on monitoring of prices of non-scheduled formulation, NPPA has fixed prices in case of 30 formulation packs under para 10(b) and companies have reduced price voluntarily in case of 65 formulation packs. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA.

QUESTION NO : 2679
ANSWERED ON : 26.08.2011

VARIATION IN THE PRICES OF SAME MEDICINES .2679

SHRI M.P. ACHUTHAN

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state :-

(a) whether Government is aware that there is a great variation in the prices of same medicines manufactured by different companies in the country;

(b) if so, the details thereof; and

(c) the measures being taken by Government to ensure the availability of quality medicines at reasonable and uniform prices in the market?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)
(a) to (c): Under the provisions of the Drugs (Prices Control) Order, 1995 (DPCO,95), the prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled. National Pharmaceutical Pricing Authority (NPPA) fixes or revises prices of scheduled drugs / formulations as per the provisions of the DPCO, 1995. Under the provisions of DPCO, 1995, no person can sell any scheduled formulation (medicine) to a consumer at a price exceeding the price notified / approved by NPPA. Therefore, there cannot be any price variation in cases of Scheduled drugs/medicines. In respect of drugs not covered under the big domestic drugs companies;

(b) whether it is also a fact that medicines outsourced from SME drug companies are sold at very high rates by multinational and big domestic companies;

(c) if so, whether Government would take any step to give relief to S.M.E. drug companies;

(d) if so, by when; and

(e) if not, the reasons therefor?

DPCO,95 i.e. non-scheduled drugs, manufactures fix the prices by themselves without seeking the approval of Government/ NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excepients, cost of R&D, cost of utilities / packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc. Since there is no control on the launch price of non-scheduled medicines it leads to price variation in the prices of similar medicines sold under different brands.

As a part of price-monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of IMS Health and the information furnished by individual manufactures are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process. Based on monitoring of prices of non-scheduled formulations, NPPA has fixed prices in case of 30 formulation packs under para 10(b) and companies have reduced price voluntarily in case of 65 formulations packs. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA. NPPA is entrusted with the responsibility of monitoring the availability of drugs and to identity shortage, if any, and to take remedial steps to make the drugs available. NPPA is carrying out this responsibility mainly through monthly field reports from the State Drugs Controller and other available information. As and when the reports for shortage of particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock and to make the drugs available. Further, the Department of Pharmaceuticals has launched 'Jan Aushadhi Campaign' with the objective of making available medicines at affordable prices for all. Under this campaign less priced quality unbranded generic medicines are being made available through 104 Jan Aushadhi Stores which are presently operational in the States/UTs of Punjab, Haryana, Uttrakhand, Odisha, Andhra Pradesh, Himachal Pradesh, Jammu & Kashmir, Rajasthan, West Bengal, Chandigarh and Delhi.

QUESTION NO : 650
ANSWERED ON : 05.08.2011

OUTSOURCES MEDICINES BEING SOLD AT HIGH RATES

650 SHRI SATYAVRAT CHATURVEDI

(a) whether Government is aware that S.M.E. drug companies manufacture medicines worth Rs. 50,000-55,000 crore annually and sell the medicines worth Rs. 20,000-30,000 crore to multinational and big domestic drugs companies;

(b) whether it is also a fact that medicines outsourced from SME drug companies are sold at very high rates by multinational and big domestic companies;

(c) if so, whether Government would take any step to give relief to S.M.E. drug companies;

(d) if so, by when; and

(e) if not, the reasons therefor?

ANSWER

MINISTER OF STATE(INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b): Small and Medium Drug Manufacturing companies are also manufacturing medicines for multi-national companies and big domestic

companies on loan/contract licenses. Under the Drugs (Prices Control) Order, 1995(DPCO, 1995), no person can sell any formulation (medicines) of price controlled category to a consumer at a price exceeding the price notified/approved by the NPPA/Government. In respect of drugs – not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government /NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities /packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG IMS(now renamed as IMS Health) and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, subject to prescribed conditions, the manufacturers is asked to bring down the price voluntarily failing with action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process.

(c) to (e): The Department of Pharmaceuticals in collaboration with the Ministry of MSME has introduced a Scheme for Schedule 'M' Compliance by SSI Units in Pharma Sector under the overall umbrella of Credit Linked Subsidy Scheme. Under the Scheme, the Pharma SSI units are eligible to get 15%(upto Rs. 15.00 lakhs)upfront capital subsidy on an institutional finance for an amount upto Rs. 1.00 crore to be availed by them for inclusion of well established and improved technology to make themselves Schedule 'M' Compliant.

QUESTION NO : 656
ANSWERED ON : 05.08.2011656

SHRI ISHWAR SINGH

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-(a) whether Government is reworking the draft Pharma Policy to incorporate changes in the National List of Essential Medicines (NLEM);

(b) if so, whether prices of most of the essential medicines have shot up and there is an urgent need to regulate the prices of such medicines;

(c) if so, the facts and details thereof; and

(d) the concrete steps Government proposes to take to gain control over essential medicines?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) to (d): The revised National List of Essential Medicines (NLEM), 2011 has recently been received from the Office of Drugs Controller General of (India). The Department of Pharmaceuticals is examining all the possibilities of controlling the prices of medicines including those covered under the NLEM, 2011.

HEALTH AND FAMILY WELFARE

QUESTION NO : 3028
ANSWERED ON : 20.12.2011

REGULATIONS OF CLINICAL TRIALS

3028 SHRI MAHENDRA MOHAN
Will the Minister of HEALTH AND FAMILY WELFARE be pleased to satate :-

(a) whether Government is aware of various reports about conduct of clinical trials on patients by

hospitals, clinics and pharmaceutical companies without their consent;

(b) if so, the details thereof;

(c) whether Government proposes to strengthen clinical trials regulations and enforce their strict compliance in the country; and

(d) if so, the details thereof along with the steps taken so far in this regard?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD) (a) & (b): Yes. A statement giving the number of cases investigated and action taken thereon for irregularities in conduct of clinical trials during the last three years and the current year is annexed.

(c) & (d): In order to strengthen the regulations relating to clinical trials, following proposals for amendments in Drugs and Cosmetics Rules, 1945 have been approved by Drug Technical Advisory Board (DTAB) a statutory advisory Committee under the Drugs and Cosmetics Act, 1940 and a draft notification GSR 821 (E) dated 18.11.2011 has also been published by the Government therefor:

1. Incorporation of effective provisions for providing financial compensation to the trial subjects in case of trial related injury or death.
2. Enhancement of responsibilities of Ethics Committee, Sponsor & Investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths. Such information has to be provided to Drug Controller General (India){DCG(I)}.
3. Amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects.

QUESTION NO : 3036
ANSWERED ON : 20.12.2011

HUMAN CLINICAL TRIAL OF CANCER VACCINE

3036 SHRI T.M. SELVAGANAPATHI

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to satate :-(a) whether it is a fact that a cancer vaccine is awaiting human clinical trial which is to be conducted in Chennai;

(b) if so, the details thereof;

(c) whether it is also a fact that this vaccine was invented by the National Institute of Immunology (NII), India and that the same has been tried on animals; and

(d) if so, the details thereof?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE(SHRI SUDIP BANDYOPADHYAY)

(a) & (b): Yes.
(c) & (d): The candidate target molecule was invented at National Institute of Immunology (NII) under the Department of Biotechnology, and was tried on rodents using different cancer cell lines. However, clinical trials have been fixed for Cancer Institute (WIA) Adyar in Chennai.

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