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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2011

Tamilnadu Pharmaceutical
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ISSUE : 12 Oct. - Nov. - Dec. 2011

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MESSAGE FROM CHAIRMAN

Dear Readers,

I have taken over as the Chairman of Tamilnadu Pharmaceutical Sciences Welfare Trust recently. At the outset, I would like to convey my advance best wishes to you for a **Happy and Wonderful New Year 2012.** I appreciate our Trust for publishing the newsletter for the benefit of Pharma Professionals. Many important Professional articles and information's are being published through this newsletter. I am happy to note that the newsletter started in the year 2009 on quarterly basis is being published continuously without any interruption. During this month we will be celebrating **"National Pharmacy Week Celebration"** between **20th and 27th.** The theme of this celebration is **"Pharmacist: A Health Care Professional".** The various Pharmacy Colleges as well as Pharma associations and Chemist and Druggist Association shall come to one forum during this week for making greater awareness about the role of Pharmacist in Manufacturing and distributing quality medicines. As Vice President of IDMA and also as a Pharma Industrialist, I advise all our young Pharmacists to work for the welfare of the Profession and also to uplift the image of Pharmacist in public.

Our Trust is making efforts for conducting Essay Competition for the B. Pharm students and also awarding prizes for the winners. It is also important to note that the Trust is awarding scholarships for the M. Pharm students. The other important aspect is, the Trust a established a library and also Pharma Information Centre for the benefit of Pharma students. All colleges shall utilise this opportunity and enrich their knowledge.

In future, we will be improving the Pharma Web newsletter as per the demand of the professionals and students. I congratulate the staffs of the Trust, Trustees and Shri. R. Narayanaswamy the Editor of the Newsletter for publishing their newsletter in a time bound manner with great interest and enthusiasm.

I request for advertisements in our Pharma Web from Industry, Trade and Academia for supporting this useful publication.

Thanking you,

S.V.VEERRAMANI

EDITORIAL

Dear Readers,

This is the 12th issue of our newsletter since inception. Our new Chairman Mr. S.V. Veerramani, Managing Director of Fourrts India Private Limited, Chennai initiated various steps to activate our Trust activities. With the blessings of our Chairman, our Trust could able to get a good tenant for our office premises at Spencer Plaza. We have also actively participating and providing necessary assistance to Indian Pharmaceutical Association, Tamilnadu Branch for conducting National Pharmacy Week Celebration being celebrated between 21st to 28th of this month. The theme of the National Pharmacy Week is **"Pharmacist: A Health Care Professional"**. During this programme our Trust will be awarding scholarship to M.Pharm students and also for the final year B. Pharm students on Essay Competition.

In this issue, we are covering articles written by Mr. Prasad, Deputy Drugs Controller, India, CDSCO (South Zone) about **"Role of CDSCO: Current Scenario"** and also delegation of power for issue of various licenses by CDSCO. The delegation of power will be really useful to the drug manufacturers as well as the importers if import licenses like Form: 10 are issued. We hope that the new Drugs Controller, India will be delegating more powers to the regional office in order to benefit the industry.

The other article on **"Call for harmonization of regulatory systems across the globe"** by Rajashri Survase – Ojha is covering all the aspects of harmonization with regard to various types of clinical trials. This article may help the manufacturers as well as regulatory bodies for proper clinical trial methods and systems for the safety of new drugs before approving for marketing.

In this issue, we have also covered the important questions and answers pertaining to Health Ministry and Ministry of Chemicals and Fertilizers on Pharmaceutical subject. Many regulatory authorities as well as Pharma professionals will get lot of statistical information from various question and answers.

We have also covered important Pharma professional news which will help our readers to update their knowledge and information. I also thank all the Pharma Companies and Colleges for sponsoring advertisements for this newsletter.

We wish all our readers a very **"Happy and Prosperous New Year 2012".**

With best regards
Mr. R. Narayanaswamy

ARTICLES

Role of CDSCO, Current Scenario

By Mr. P.B.N. Prasad

Deputy Drugs Controller (I), CDSCO, South Zone, Chennai

Functions Of CDSCO

- Laying down standards of drugs, cosmetics, diagnostics and devices.
- Laying down regulatory measures, amendments to Acts and Rules.
- To regulate market authorization of new drugs.
- To regulate clinical research in India.
- To approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, Large Volume Parenterals and Vaccines & Sera.
- To regulate the standards of imported drugs.
- Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
- Testing of drugs by Central Drugs Labs.
- Publication of Indian Pharmacopoeia.

Other Functions

- Coordinating the activities of the State Drugs Control Organizations to achieve uniform administration of the Act; and policy guidance.
- Guidance on technical matters.
- Participation in the WHO GMP certification scheme.
- Monitoring adverse drug reactions (ADR).
- Conducting training programmes for regulatory officials & Govt. Analysts.
- Distribution of quotas of narcotic drugs for use in medicinal formulations.
- Screening of drug formulations available in Indian market.
- Evaluation/Screening of applications for granting No Objection Certificates for export of unapproved/banned drugs.

Delegated Powers to CDSCO Zonal Offices

- Issue of NOC for Dual Use
- Issue of NOC for Approved / Unapproved, Banned drugs
- Issue of NOC for Test Licence in Form 29
- Issue of Licence in Form 12B
- Renewal of Blood Bank Licences

Procedure for issue of NOCs/Licences

- Receipt of the application and allocating the Diary No.
- Giving the acknowledgement at the time of receipt of the application
- Scrutiny and review of the documents alongwith the application as per the guidelines issued by Drugs Controller General (India)
- If complied NOC(Dual Use, Export only, Form 29)/Licence in 12B is issued
- If not complied a query letter is issued to the applicant
- On satisfactory compliance with respect to the query letter issued, NOC/Licence is issued
- A status report of the application – On Scrutiny, 1st Response, 2nd Response etc., Ready for Issue/Issued is displayed on the LCD Screen in the office premises during working hours

- In addition to the above functions, there is no change in the existing activities of the Zonal Offices of the CDSCO, such as, Joint Inspections for Blood Banks, Large Volume Parenterals, Vaccines, Medical Devices, rDNA Products etc., for Grant / Renewal.
- Joint Inspections for Grant of Approval of Analytical Laboratories for testing
- Joint Inspections for Certification of Pharmaceutical Products as per WHO/GMP guidelines
- Inspection of Bio-equivalence Study Centres as directed by the Drugs Controller General of India from time to time
- Detecting spurious, adulterated or not of standard quality drugs and following suitable actions as per the provisions of Drugs & Cosmetics Act
- Any other functions as directed by the Directorate from time to time

Requirement for the Submission of an application for issue of "No Objection Certificate" (NOC) for the manufacture of unapproved/approved New Drugs in Form -29 for the purpose of examination, test & analysis (Excluding for clinical trial purpose) for drugs other than Biologicals/ Medical Devices/ Diagnostic Kits

Introduction

A manufacture can obtain license in Form – 29 from the concerned State Drug Department, under whose jurisdiction the manufacturing facility lies for the manufacture of any drug in small quantities for the purpose of examinations, test or analysis

only, if the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a license in Form – 25 or Form – 28 in respect of such drugs he shall, before commencing such manufacture, obtain a license in Form – 29.

Purpose

Requirement for the Submission of an application for issue of "No Objection Certificate" (NOC) for the manufacture of unapproved/ approved new drugs in Form–29 for the purpose of examination, test & analysis (Excluding clinical trial purpose) for drugs other than Biologicals/ Medical Devices/ Diagnostic Kits). This guideline will corroborate various commonly found aspect of granting licence in Form –29 for the manufacture of specific quantities of drugs under the provisions made in Part – VIII of Drugs & Cosmetics Act & Rules 1945.

Scope

This document is applicable only for the applications for obtaining Form – 29 NOC from Zonal Offices for Form – 29 manufacturing licence from State Licensing Authority for drugs excluding Biological/ Medical Devices/ Diagnostic Kits

Procedure

Under the provision of Rule – 89 it is mentioned that

"in the case of a drug, the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form – 29 shall be granted unless the applicant produces a certificate from the "Licensing Authority" mentioned in Rule 21, to the effect that there would be No Objection to such license being granted".

Manufacture of API (Bulk) for examination, test & analysis only;

- Name of Drugs
- Class of Drugs
- Indication of Drugs
- Address of the facilities where drugs is to be manufactured
- List of equipments
- Details of premises (layout plan) & manufacturing process
- SOP of Analytical procedure & manufacturing process
- Flow Chart of manufacturing Process.
- List of Staff their qualification & experience.
- Details of raw materials
- Details of the test are to be performed with the drug
- Published Literature
- Status of Drug whether approved/unapproved

Manufacture finished formulation for examination, test & analysis only;

- Name of Drugs
- Class of Drugs
- Indication of Drugs
- Dosages & Strength of the formulation
- Route of administration
- Composition of product
- SOP of Analytical procedure & manufacturing process
- Flow Chart of manufacturing Process.
- List of Staff their qualification & experience.
- Details of raw materials
- Details of the test are to be performed with the drug
- Address of the facilities where drug is to be manufacture
- List of equipments
- Details of premises & manufacturing process
- Published literature of the proposed formulations

Manufacture of Investigational New Drugs (IND) for examination, test & analysis only;

- Details of raw materials
- Details of the test are to be performed with the drug
- Address of the facilities where drug is to be manufactured
- List of equipments
- Details of premises & manufacturing process
- Published literature for the proposed formulations/Bulk
- INN (International Non-proprietary Nomenclature)
- Material safety data sheet
- Structural Formula & Molecular Formula

Note:-

If the drugs covered under NDPS Act or for veterinary use, the permission from Narcotics Commissioner of India or permission from Department of Animal Husbandry, Ministry of Agriculture & Fisheries, Govt. of India respectively has to enclose along with applications.

Only actual manufacturer has to apply for NOC along with all relevant documents as mentioned above.

Undertaking stating that the product to be manufacture under Form – 29 licence will not be utilised for any Clinical Trial or any commercial purpose.

INTRODUCTION

A manufacturer holding valid license copy in Form -25 and Form- 28 can obtain No Objection Certificate from Zonal offices of Central Drugs Standard Control Organisation (CDSCO) for export purpose only for Approved / Unapproved New drug / Banned drug in India.

Documents to be submitted

Covering Letter:-

The covering letter is an important part of the application and should clearly specify the intent of the application.

The list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter.

Documents to be submitted(Contd..)

- The covering letter mentioning list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size along with quantity and country to be exported duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm.
- Each application should be made by the manufacturer only.

Purchase Order:-

a.)Order from the foreign buyer either in the name of manufacturer or in the name of trader mentioning list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size duly signed by the competent authority with specific destination point of the importing country.

In case of purchase order in the name of trader further a letter from the trader in the name of manufacturer is required to be submitted along with the application

b.)It should be signed by the competent authority/person with a valid purchase order no. and recent date not more than 6 month prior to the application made by the firm.

Manufacturing License:-

License issued by the State Licensing Authority should be enclosed along with each application for the required location to manufacture the drug for export purpose.

Performa Invoice:-

a. A copy of Performa invoice from the importing country should accompany with application for import of unapproved Active Pharmaceutical Ingredients, used in the drug formulation.

b. A copy of Performa invoice duly signed by the competent authority should be addressed to the manufacturer mentioning the required quantity of the bulk drug.

Registration Certificate:-

a) For the export of drugs which are banned in India by Central government, which coming under list of drugs prohibited for manufacture and sale through gazette notifications under section 26a of drugs & cosmetics act 1940 by the ministry of health and family welfare.

b) A copy of registration certificate from the specific importing country along with composition and strength of the drug should accompany with the application

c) Registration certificate should be provided in the name of manufacturer.

- While processing such applications the following conditions shall be taken into consideration:
- The application shall provide copy of valid export order and NOC will be issued on a case by case basis against each such order.
- The applicant shall identify the premises where the drug will be manufactured for export.
- The applicant should mention whether the batch to be exported has undergone Quality control testing or shall be tested at the destined site.
- The applicant shall ensure that the drug(s) manufactured on the basis of NOC given as per (1) above its exported and that no part of it is diverted for domestic sale in India.
- The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment despatched, remaining stock of drug and related raw materials and intermediates in hand.
- The applicant shall ensure physical destruction of all un exported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.
- The applicant shall ensure that the drug for which NOC has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment despatched, remaining stock of drug and related raw materials and intermediates in hand.
The applicant shall ensure physical destruction of all un exported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.
The applicant shall ensure that the drug for which NOC has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

Introduction

A manufacture can obtain license in Form – 29 from the concerned State Drug Department, under whose jurisdiction the manufacturing facility lies for the manufacture of any drug in small quantities for the purpose of examinations, test or analysis only, if the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a license in Form – 25 or Form – 28 in respect of such drugs he shall, before commencing such manufacture, obtain a license in Form – 29.

Purpose

Requirement for the Submission of an application for issue of "No Objection Certificate" (NOC) for the manufacture of unapproved/approved new drugs in Form – 29 for the purpose of examination, test & analysis (Excluding clinical trial purpose) for drugs other than Biologicals/ Medical Devices/ Diagnostic Kits). This guideline will corroborate various commonly found aspect of granting licence in Form – 29 for the manufacture of specific quantities of drugs under the provisions made in Part – VIII of Drugs & Cosmetics Act & Rules 1945.

Scope

This document is applicable only for the applications for obtaining Form – 29 NOC from Zonal/Sub-Zonal offices for Form – 29 manufacturing licence from State Licensing Authority for drugs excluding Biological/ Medical Devices/ Diagnostic Kits.

Procedure

Under the provision of Rule – 89 it is mentioned that

"in the case of a drug, the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form – 29 shall be granted unless the applicant produces a certificate from the "Licensing Authority" mentioned in Rule 21, to the effect that there would be No Objection to such license being granted".

In light of the above, it is desirable that the application should be submitted to the respective Zonal/Sub-Zonal offices of CDSCO where the actual manufacturing site is located. The applicant (Manufacturer) should submit document as per the following three categories;

Manufacture of API (Bulk) for examination, test & analysis only

- Name of Drugs
- Class of Drugs
- Indication of Drugs
- Address of the facilities where drugs is to be manufactured
- List of equipments
- Details of premises (layout plan) & manufacturing process
- SOP of Analytical procedure & manufacturing process

Manufacture of API (Bulk) for examination, test & analysis only (Contd..)

- Flow Chart of manufacturing Process.
- List of Staff their qualification & experience.
- Details of raw materials
- Details of the test are to be performed with the drug
- Published Literature
- Status of Drug whether approved/unapproved

Manufacture finished formulation for examination, test & analysis only

- Name of Drugs
- Class of Drugs
- Indication of Drugs
- Dosages & Strength of the formulation
- Route of administration
- Composition of product
- SOP of Analytical procedure & manufacturing process
- Flow Chart of manufacturing Process.
- List of Staff their qualification & experience.

Manufacture finished formulation for examination, test & analysis only(Contd..)

- Details of raw materials
- Details of the test are to be performed with the drug
- Address of the facilities where drug is to be manufactured
- List of equipments
- Details of premises & manufacturing process
- Published literature of the proposed formulations

Manufacture of Investigational New Drugs (IND) for examination, test & analysis only

- Name of Drugs
- Class of Drugs
- Indication of Drugs
- Dosage & strength of the formulation
- Route of administration
- Composition of product
- SOP of Analytical procedure & manufacturing process
- Flow Chart of manufacturing Process
- List of Staff their qualification & experience

Manufacture of Investigational New Drugs (IND) for examination, test & analysis only(Contd..)

- Details of raw materials
- Details of the test are to be performed with the drug
- Address of the facilities where drug is to be manufactured
- List of equipments
- Details of premises & manufacturing process
- Published literature for the proposed formulations /Bulk
- INN (International Non-proprietary Nomenclature)
- Material safety data sheet
- Structural Formula & Molecular Formula

Note:-

If the drugs covered under NDPS Act or for veterinary use,the permission from Narcotics Commissioner of India or permission from Department of Animal Husbandry, Ministry of Agriculture & Fisheries, Govt. of India respectively has to enclose along with applications.

Only actual manufacturer has to apply for NOC along with all relevant documents as mentioned above.

Undertaking stating that the product to be manufacture under Form – 29 licence will not be utilised for any Clinical Trial or any commercial purpose

The dual use permissions are usually requested by the manufacturer of bulk drug using one of the bulk drugs as starting material based on the approval of State Licensing Authorities. The dual use permission may also be sought by the other industries like food industries etc. which uses raw bulk substance in lower strength than approved as drug by this organisation. Similarly, the Animal feed Industry makes application for the import of raw materials for the exclusive use as animal feed. The list is enclosed with this guidelines is only for reference purpose. The disposal of application is purely dependent on the intended use and its technical examination keeping in view the applicability of the status of drug.

The importers of dual use have a responsibility to undertake due diligence before making application for import of material for which following points may be important for consideration:

- The drugs already registered for import,
- Approval status of usages of imported item in the country (alone or in combination with other drugs),
- International s tatus (e.g. in most of the countries multivitamins are not considered as drugs hence regulated differently),
- Technical survey through Martindale extra pharmacopeia etc.

The application for dual use import may be made well in advance before the actual import to facilitate technical review for consideration.

The permission for dual use items will be granted by Dy. Drugs Controller (India) of the respective Zones.

Based on the intended use of the product, the drugs that are falling under Schedule-D of Drugs and Cosmetic Rules have been categorised into:

- ❖Drugs meant for Non- medicinal use.
- ❖Drugs meant for Animal feed supplement, Feed premix.
- ❖Drugs meant for further processing / conversion to other drug.

Drugs Meant for Non- Medicinal Use

The following documents are required to be submitted for the items specified below;

- Aluminium Hydroxide
- Benzoyl peroxide
- Calcium Carbonate
- Cinchonine
- Citric acid
- Coumarin
- Cysteamine HCl
- Di calcium phosphate
- Diflorasone Base
- Disodium carbonate
- Disopyramide base
- Empty hard gelatine Capsules with TSE/BSE free
- certificate and GMP declaration of the manufacturing firm.
- Estrone
- Glycerine with pharmacopeial grade
- Guanidine hydrochloride

Drugs Meant for Non- Medicinal Use (Contd..)

- Heavy Magnesium Carbonate
- Hesperidine
- Hydrogen Peroxide Pharmacopeial grade
- Isoxepac
- Magnesium hydroxide
- Magnesium oxide
- Magnesium Sulphate
- Mannitol (not for parenteral use)
- Mixed tocopherols 50%
- Monensin Sodium
- Simethicone Emulsion
- Triacetin
- Zinc Gluconate
- Manganese Sulphate
- Alpha Lipoic Acid
- Zinc Oxide
- Any Other Drug having Dual Use which may find suitable to be included in list.

to the Zonal Office for grant of necessary permission under Schedule - D, preferably before importing the consignment.

Covering letter- The applicant should submit covering letter by clearly specifying purpose of application, the drugs to be imported, the intended use of the drug, quantity to be imported, name and address of the manufacturer and list of documents that are being enclosed (Index with page numbers). The covering letter should be duly signed and s tamped by the Authorised Signatory, indicating name and Designation of the Authorised Signatory. The pages of the application should be numbered and should be accompanied with index.

Legal Undertaking- The applicant has to submit Legal Undertaking on Rs.100 stamp paper as per the proforma given Under **Annexure-I** (If the drug is imported by the actual User, Legal Undertaking as per the proforma provided in

Annexure-II should be obtained from the Trader. The Trader has to retain such undertaking issued by the actual user for any inspection carried out by the regulators).

A copy of valid Manufacturing Licence from Actual User for the products to be manufactured, issued by the Competent Authority wherein the imported drug will be used.

A copy of valid trade licence / Excise Registration Certificate from importer.

- A copy of letter (notarised) issued by the Competent Authority stating that the imported drug will be used in the manufacture of said finished product and not as an active principle.
- A copy of Certificate of Analysis of the drug to be imported, issued b y t he manufacturer in the country of origin (not by exporter).
- Detailed Technical Literature of the drug to be imported.
- For subsequent permission, Reconciliation data of previously permitted quantity in addition to above details

Drugs meant for Animal feed supplement, Feed premix

Before grant of NOC for release of items stated below;

List of the feed grade items which requires NOC from Port Office (CDSCO) for exclusive use in animal feed industry as an animal feed supplement, feed premix.

I. Amino Acids (granular)

1) L-Lysine Mono HCL 99% Feed grade
2) L-Lysine Sulphate 65% Feed grade
3) DL-Methionine 99% Feed grade
4) L-Threonine Feed Grade

II. Vitamin Premix

1) Vitamin AD3 Feed grade 1000:200
2) Vitamin E 50% Feed grade
3) Vitamin D3 0.5 miu/gm feed grade
4) Vitamin B2 80% feed grade
5) Biotin 2% Feed grade
6) Vitamin mineral Premix feed grade (as per formula)
7) Choline Chloride 50% & 60% on Corn Cob carrier

III. Phosphates

1) Mono Calcium Phosphate (MCP) 22% Feed grade
2) Di Calcium Phosphate (DCP) 18% feed grade.

IV. Antibiotic / Antibacterial Feed Additives

1) Chlortetracycline 15% Feed grade
2) Dichlozuril 1% feed grade
3) Zinc Bacitracin 10% feed grade
4) BMD-Bacitracin Methyl Disalicylate 15% Feed grade
5) Tylosin Phosphate 10% premix feed grade
6) Colistin Sulphate - % Premix Feed Grade
7) Clopidol 25% Feed Grade

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V. Anticoccidiostats

1) Maduramycin 1% Feed grade
2) Salinomycin 12% Feed grade

Any other product included in the list of poultry/ Animal Feeds shall be included after approval from the Animal Husbandry Department.

The concerned Port Officer should verify / examine following documents -

Legal Undertaking- The applicant has to submit Legal Undertaking on Rs.100 stamp paper as per the proforma given under Annexure I. (If the drug is imported by the actual User, Legal Undertaking as per the proforma provided in **Annexure-II** should be obtained from the Trader. The Trader has to retain such undertaking issued by the actual user for any inspection carried out by the regulators).

Purchase order / Proforma invoice of the material to be imported.

NOC from the Ministry of Animal Husbandry in favour of importer /manufacturers, if any.

A copy of valid trade licence / Excise Registration Certificate from importer.

- A copy of letter (notarised) issued by the Competent Authority stating that the imported drug will be used in the manufacture of said finished product and not as an active principle but as feed.
- A copy of Certificate of Analysis of the drug to be imported, issued by the manufacturer in the country of origin (not by exporter).
  Detailed Technical Literature of the item to be imported.
- For subsequent permission, Reconciliation data of previously permitted quantity in addition to above details.

Drugs meant for further processing/conversion to other drug

For the import of any substance which attracts the definition of Drug as per the Drugs and Cosmetics Act 1940 for further processing / conversion to manufacture of other drugs, shall require NOC from Zonal Office for each consignment.

e.g.:- Erythromycin Thiocyanate for the manufacture of Erythromycin salts, Penicillin G Potassium for the manufacture of Penicillin drugs. Such permissions are considered for those manufactures which does not have manufacturing permission in the country for imported drug, however they got permission for manufacture of other drug using imported drug.

The following documents are required to be submitted to the Zonal Office for grant of necessary permission under Schedule- D, preferably before importing the consignment. Covering letter- The applicant should submit covering letter by clearly specifying purpose of application, the drugs to be imported, quantity to be imported, name and address of the manufacturer and list of documents that are being enclosed (Index with page numbers).

The covering letter should e duly signed and stamped by the Authorised Signatory, indicating name and Designation of the Authorised Signatory.

A copy of Valid Drug Manufacturing Licence for the Drug to be manufactured, issued by the Drug Licensing Authority wherein the imported drug will be used.

A copy of Master Formula Record of the product to be manufactured Signed and Stamped by the Authorised Signatory of the Firm.

A copy of Certificate of Analysis of the drug to be imported, issued by the manufacturer.

Detailed Justification of the quantity of Drug to be imported.

Brief Manufacturing Process including Flowchart wherein the imported product will be used.

Detailed Technical Literature of the drug to be imported.

For Subsequent permission, Reconciliation data of previously permitted quantity in addition to above details.

(List of bulk drugs already registered is annexed as Annexure III)

(The import of drug under dual use for purification or rendering it sterile will not be considered under dual use)

Annexure I

Legal Undertaking for the Import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Actual Users to The Central Drugs Standard Control Organisation (CDSCO) Zonal office.

I/We..... S/o..... having premises at ..... aged about .....do hereby solemnly affirm state and undertake as under:

1. That I am the importer of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry No.....dated.....
2. That I undertake to use..... (Quantity) of above said drug for Non-Medicinal purpose/ as a phrama aid / as a drug intermediate to manufacture other drugs only.(delete whichever not applicable).
3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.
4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of (Name of the drug) as and w hen required.
5. I state that that consignment document like Certificate of Analysis, Bill of Entry, invoice etc. clearly mentions Not for Medicinal Use or (for use as pharma aid).
6. That the bags/containers carrying (Name of the drug) along with other requirements of labelling and packaging also mentions – Not For Medicinal Use or (for use as pharma aid).

DEPONANT

VERIFICATION

Verified on this .....day of..... (Month & Year) that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from.

DEPONANT

Legal Undertaki ng for the import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Importer/ Trader to The Central Drugs Standard Control Organisation (CDSCO) Zonal Office.

I/We.....S/o..... having premises at .....aged about .....do hereby solemnly affirm state and under take as under:

1. That I am the importer/trader of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry/Purchase order no.....dated.....
2. That I undertake to sell..... (quantity) of above said drug for Non - Medicinal purpose/as a phrama aid / as a drug intermediate to manufacture other drugs only (delete whichever not applicable)
3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.
4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of said drug as and when required.
5. That the bags/containers of the said drug along with other requirements of labelling and packaging also mentions “Not For Medicinal Use”.
6. That the data of my previous transaction is annexed with this undertaking (Optional in cases of subsequent transaction).

DEPONANT

VERIFICATION

Verified on this .....day of..... (Month & Year) that the contents of my above under taking are true and that no part it is false and that nothing material has been concealed here from.

DEPONANT

Important Points for consideration

- The application should be complete before submission to the authorities.
- Application for dual use clearance is advised to be made by the manufactures or its authorised agent or importer to the authorities well in time for technical review for consideration preferably before the actual import to avoid demurrages. It may be advised that a period of two months before the actual import will be effective for smooth clearance of consignment.
- The consignment label, bills, invoices etc. in respect of imported items should clearly have indelible marking for its intended use.
- The applicant for manufacture of a drug using imported drug must have Master Formula Record duly attested by the Licensing authority for import application.
- The import of drug under dual use for purification or rendering it sterile will not be considered under dual use.
- The import permission for dual use item can be considered to actual users for the period of one year.
- If application is made to the Port officer, it will be forwarded with remarks to the Zonal head of CDSCO for review and consideration preferably by e mail / fax. The NOC from Zonal Head via e mail / fax will be sufficient for release.
- The Zonal office will maintain data for such releases.

Permit for import of small quantities of Drugs for personal use under Form 12B of the Drugs & Cosmetic Rules

- The contents of documents are scrutinized as per Form- 12A.
- After scrutiny, the checklist is prepared with details of documents submitted.
- If all documents are in order, permit may be issued on the same day.
- In case of doubtful documents, investigation may be got carried out for verification of the facts before issuance of the permit.

Procedure for approval of Licence

The following documents are required for approving the Blood Bank Licence issued by State Licencing Authority

Documents required for approval of Licence:-

- Forwarding letter from State Licencing Authority
- Renewal certificate in Form26G in triplicate duly signed by State Licencing Authority
- Joint Inspection Report
- Recommendations of the Inspecting Team
- Compliance verification report, if any

Call for 'harmonisation of regulatory systems across the globe'

The Express Pharma, Vol 6, Sep. 2011

By **Rajashri Survase-Ojha,** Director and Founder, Raaj Global Pharma Regulatory Affairs Consultants and Onkar Deshmukh, currently a student at The University of Greenwich, UK

Harmonisation of the multiple regulatory systems in the pharmaceutical industry is very necessary for a hassle-free, safe and expeditious approval mechanism Regard this whole world as our human body and think what would happen if there is no synchronisationor our body is inharmonious. The result is known to everyone and one cannot consider his/her body to be disharmonious. We assume that some of our body parts are quite important for us to live such as heart, lungs, liver etc. and we eventually lean towards their maintenance or become more concerned about them. Even though it is reasonably true to a certain level, we cannot turn our back on other parts of our body as they aptly do their part to maintain the harmony on the whole and as a result we are able to lead a whole life. This example can be corelated with the pharmaceutical regulatory system.

As we know the concept of regulated and semi-regulated markets and in connection with this presume that our brain, heart and liver are the regulated markets of body and rest of all parts as semi-regulated. Will that do? Of course not because every part of our body (here, every region) is significant and every cell (here, every pharma company) of that part makes their best. They should be regulated at the same level, like different parts of the human body. If this had not been so, I would have not been here to write this stuff. Same theory can be applied to a regulatory system in pharma domain on the global level. I am at a loss to understand why there is a difference as 'regulated and semi-regulated markets', why US, EU and Japan are considered as highly regulated markets when people are same throughout the world?. The final aim of every pharma company remains generating products that are of best quality, efficacy and are safe. Every company plans to do the same and so should be the rules to be implemented.

Every regulatory authority should be like a 'segment' of the same human brain and not like separate brains. If one brain can control the whole body then why don't regulatory bodies come together and form a unique brain to harmonise the whole system?

Now it is the time to start the ball rolling by setting up a totally harmonised system for the regulation of pharma industries. To start off, the harmonisation of pharma regulation on the global level can give the whole pharma world a new lease on life.

To broach the subject, we are acquainted with the ICH [International Conference on Harmonisation of.....] which is a inimitable venture that brings together the regulatory authorities of Europe, Japan and the US along with the experts from the pharma industries within these three regions to discuss the scientific and technical aspects of product registration. So far as these three regions are considered, there seems a homogeneity in the regulation which is pretty advantageous and inspiring in safety, quality and efficacy standpoint. For instance, the concept of CTD, a common technical document that is well thought-out by the ICH. This document encompasses the five different modules covering all the essential data that is quite substantial for the effective regulation.

At this instant, I would like to expound upon few ideas that can be implemented or changed in order to have a better and greater harmonisation by taking on board the notion of CTD and e-CTD [electronic-CTD]

ultimately to save precious time and cost to bring the best drug product into market. CTD is a common format for the preparation of a well-structured and organised application containing technical documents that will be submitted to regulatory agencies. As stated above, CTD has been accepted by three major regional agencies namely Japan, Europe and US. CTD being a common format for the technical documentation is projected to condense the time and its wherewithal needed to prepare and compile applications for product registration and which eases the application appraisal process and aids communication amidst the regulatory authority and the applicant. It also simplifies the exchange of regulatory data among regulatory agencies. CTD has been obligatory requirement in Europe and Japan. The US FDA has not made it compulsory while submitting the marketing applications (MA) but it has been highly recommended and from 2012 it will be mandatory to US also.

However, this concept should not be limited only to these three major regions rather every region in the world must tag along this common technical format as it has been proved to be of much assistance in all point of view so it should be enforced for each country to phase in the harmonisation at the end of the day. Nevertheless, it is significant to understand that, CTD endorses a format for submission of documents in a particular way and was not designed to indicate what studies are required for an actual product. The CTD comprises five modules namely,

Module 1: Administrative and prescribing information (not part of CTD)
Module 2: CTD summaries.
Module 3: Quality part (CMC).
Module 4: Non clinical part.
Module 5: Clinical part.

Harmonising the CTD

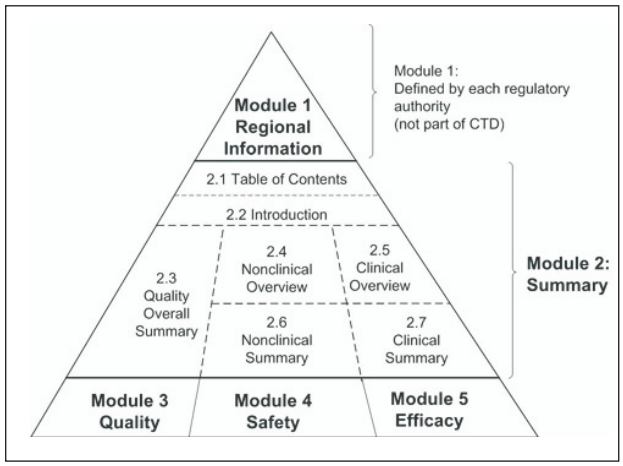
Out of these five modules, module 1 is not part of CTD and may differ in certain conditions from region to region but on the contrary, module 2-5 can be made compulsory and information or content of which should be identical for each country.

However, if there are certain requirements for the particular zone/region those can be included as a subsection in one of the five modules to help the regulatory authorities get all the necessary data (e.g. module 3.2 R, regional information).

When it comes to a matter of communication, it all boils down to a language that has universally accepted. The content of CTD and e-CTD must be in the English language, being universally accepted, with the intention of minimising time and cost it takes for translation and linked activities. Only patient information leaflet (PIL) could be kept in local language (country-specific) from the customer or patient point of view. Braille language can be used for blind people across the globe.

Also the content of Quality Module3- CMC i.e. each section and sub-sections for 'Drug Substance' and 'Drug product' should be harmonised for different range of products (for example, tablets, capsules, liquid orals, ointment-creams, parenterals etc).

Furthermore, there may be some documents that are generated externally in laboratories. For example, analytical reports, CoA, chromatographs, IR, NMR, DSC spectra, figures etc. It expects to have some definite guidelines for headers, footers, naming convention, scale etc for such documents. Additionally,



as for the herbal products, veterinary products it can also be presented in the CTD and/or e-CTD format.

Until now, the discussion was based on the harmonisation of the common technical format and its content for product registration for every region in the world but apart from this there are few things that also need overall global harmonisation. Such as fees structure, approval timings, regulatory systems (US, EU, Japan, Asian countries (ACTD), Rest of the World (Row), different terminologies used for same types of applications (e.g. IND/IMPD, or ANDA/ANDS).

For getting a single drug product MA across the globe, an applicant has to go through various cumbersome filing and submission process along with countryspecific requirements, form fee, agents fees, different formats, legal documentation etc which is really time consuming, costly and tedious. As we know the fact that US follows different regulatory systems for approval of IND/NDA/ANDA/BLA etc. whereas Europe follows national procedure, DCP, CP, MRP etc

Similarly South Africa follows MRF-1/2 process whereas Asian countries follows ACTD format along with their country-specific system and fees. UAE, follows their own MoH system, Japan (MHLW) whereas 'RoW=Rest of the World' follows different procedures.

Fees

In the ICH region also the fees structure is different for different countries but as for other areas there can be some difference. If we think of the regulation on the global level then the matter of the fees should also be taken into consideration. Whatever is the currency, fees can be determined according to types and timings of submissions. For instance, one particular fees structure for dossier submission, one definite fee constitution
for further changes in the submission or late submissions fees etc. There can be a facility where an applicant can pay the full fees at their local point.

Specific time period for the approval

Above and beyond, the approval timings may vary from agency to agency but there must be some specific time period for the approval or its stages like starting from dossier review, Technical evaluation, validation, inspection until overall approval. That is the time between the dates imprinted on receipt and the date on the certificate or letter that permits the legal marketing authorisation.

Uniformity between RX and non-Rx drugs

One more thing that needs an emphasis is the uniformity of the prescription and non-prescription drugs. There are various types of drugs that have been banned in some countries and on the other hand, in some regions their use is still at full tilt. For example, certain pain killers. Hazardous side effects do not rely on Specific atmosphere or people so the regulatory authority must keep an eye on such matters.

With all the above discussions; we would also like to suggest the term to be used as 'GTD= Global Technical Dossier' once we accept the harmonisation of regulatory system global.

Towards a GTD

In the nut shell, the ultimate goal of any health authority is to 'protect public health' and to check whether the drugs or drug products manufactured and distributed in any country are safe, of good quality and effective in whatever dose prescribed.

Nonetheless, for all this an applicant needs to submit an application along with dossier to different regulatory bodies with the necessary information as per respective country-specific format. Adopting the CTD and e-CTD formats along with uniformity in content, fees structure, filing and approval process, language would really help each country and region get the hassle free system which will eventually be safe, qualitative and effective for human beings.

Also it will help to save the time to reach the drug product to market and to patient.

Hence, experts from all regions should take a call on 'harmonisation of regulatory system across the GLOBE'. Also the term 'GTD= global technical dossier' could be used in future in ICH regions and by all other health authorities worldwide.

FORTHCOMING EVENTS

63 rd IPCA – BANGALORE

Date: The 63rd Indian Pharmaceutical Congress will be held from 16th to 18th December 2011 at Bangalore.

Venue: Bangalore International Exhibition Centre (BIEC)

Registration:

Category	Up to 31-10-2011
IPGA/AIDCOC/APTI/IPA/IHPA members	3000 + 315
Non members	4500 + 473
Spouse & accompanying members	2000 + 210
Student delegates	2000 + 210

- You can download the registration form from www.ipcbangalore.com
- Duly filled registration form & DD / Pay order in favor of 63rd **INDIAN PHARMACEUTICAL CONGRESS, BANGALORE (BANK: STATE BANK OF MYSORE S.B. A/C NO. 64075732678)** is to be submitted before the deadline.
- Acknowledgment & the receipt of registration will be sent to the email mentioned in the registration form & it is compulsorily submitted during registration.
- Student must enclose individual bonafide certificate from the Head of the institution.
- Registration fees is not refundable & non transferable.

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
NOTIFICATION
New Delhi, the 12th October, 2011

G.S.R. 752(E). - Whereas the Central Government if satisfied that the use of the drug letrozole for induction of ovulation in anovulatory infertility is likely to involve risk to human beings and whereas safer alternatives to the said drugs are available;

And whereas, the Central Government is satisfied that it is necessary and expedient to regulate by way of suspension of manufacture, sale and distribution of the drug for the said indication in the public interest;

Now therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby suspends the manufacture for sale, sale and distribution of the following drug with immediate effect.

'Letrozole for induction of ovulation in anovulatory infertility'.

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

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
CORRIGENDUM
New Delhi, the 29th October, 2011

G.S.R. 733(E). - In the notification of Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare No. G.S.R. 426(E), dated 19th May, 2010 published in Part II, Section 3, Sub-section (i) at page 1-22 of Gazette of India, Extraordinary and read with Corrigendum G.S.R. 263(E), dated 30th March, 2011, at page 1, sub-rule (2) of rule 1, Shall read as follows, -

"(2) They shall come into force with effect from 1st day of April, 2012."

[F.No.X-11014/4/2006-DFQC]
L.C. GOYAL, Addl. Secy. & Director General (CGHS)

Foot Note: The principal rule were published in the Gazette of India vide Notification No. F.28-10/45-H(I), dated 21st December, 1945 and last amended vide Notification number G.S.R. 101(E), dated 18th February, 2011.

NOTE : Government of India issued the above notification to implement import registration of cosmetics from 1st April, 2012

NEWS

Immune System Discoveries Win Nobel Prize for Medicine

Bruce Beutler and Jules Hoffmann won jointly "for their discoveries concerning the activation of innate immunity" and Ralph Steinman "for his discovery of the dendritic its role in adaptive immunity".

Three scientists, who unlocked secrets of the body's immune system, opening doors to new vaccines and cancer treatments, won the 2011 Nobel Prize for medicine on Monday. American Bruce Beutler and French biologist Jules Hoffmann, who studied the first stages of immune responses to attack, share the $1.5 million award with Canadian-born Ralph Steinman, whose discovery of dendritic cells in the 1970s is key to understanding the body's next line of defence against disease. "This year's Nobel laureates have revolutionised our understanding of the immune system by discovering key principles for its activation," the award panel at Sweden's Karolinska Institute said in a statement in Stockholm.

Lars Klareskog, who chairs the prize-giving Nobel Assembly, told Reuters: "I am very excited about what these discoveries mean. I think that we will have new, better vaccines against microbes and that is very much needed now with the increased resistance against antibiotics." Beutler, 53, is based at the Scripps Research Institute in La Jolla, California. Luxembourg-born Hoffmann, 70, conducted much of his work in Strasbourg. They will share half the 10 million Swedish crowns ($1.46 million) of prize money.

Self-Defence

The work of the three scientists has been pivotal to the development of improved types of vaccines against infectious diseases and novel approaches to fighting cancer. The research has helped lay the foundations for a new wave of "therapeutic vaccines" that stimulate the immune system to attack tumours. Better understanding of the complexities of the immune system has also given clues for treating inflammatory diseases, such as rheumatoid arthritis, where the components of the self-defense system end up attacking the body's own tissues. Beutler and Hoffmann discovered in the 1990s that receptor proteins act as a first line of defense, innate immunity, by recognizing bacteria and other microorganisms. Steinman's work, explained how, if required, dendritic cells in the next phase, adaptive immunity, kill off infections that break through. Understanding dendritic cells led to the launch of the first therapeutic cancer vaccine last year, Dendreon's Provenge, which treats men with advanced prostate cancer. "We live in a dangerous world. Pathogenic microorganisms threaten us continuously," the Nobel panel said, describing the work over the decades in understanding our defenses. Medicine, or physiology, is usually the first of the Nobel Prizes awarded each year. Prizes for achievements in science, literature and peace were first awarded in 1901 accordance with the will of dynamite inventor and businessman Alfred Nobel. The award citation noted that the world's scientists had long been searching for the "gatekeepers" of immune response. Hoffmann's pioneering research was conducted on fruit flies, highlighting how key elements of modern human biology have been conserved through evolution. The immune system exists primarily to protect against infections but it can also protect against some cancers by targeting rogue cells before they proliferate. Sometimes, however, the immune system goes into overdrive and attacks healthy tissue, leading to autoimmune inflammatory diseases, such as type 1 diabetes and multiple sclerosis, as well as rheumatoid arthritis. The effect is often compared to "friendly fire, when troops hit their own comrades in combat. Beutler told Reuters he had learnt of his prize by e-mail and had to search online to make sure it was true: "I finally found it on Google News.

Source: *The Economic Times, 4th October 2011*

Diabetes Amidst Undernourishment

NEERAJKAUSHAL
Associate Professor, Columbia University

Diabetes and undernourishment — one is an ailment historically linked with prosperity, the other normally afflicts the poor. One is usually a result of high calorie food intake and overfeeding with little exercise; the other is simply lack of food. One generally attacks at older ages; the other is more common among the very young. India has an abundance of both undernourished children and adults with type 2 diabetes. About a third of the world's underweight and stunted children under the age of 5 live in India. A child less than 5 is almost twice as likely to be chronically underweight in India as in sub - Saharan Africa. We also have the highest number of adults with type 2 diabetes (henceforth referred to as diabetes) and their number is growing rapidly — having doubled over the past 10 years. India has a higher rate of diabetes than many European countries with much higher levels of economic prosperity.

Research shows that these two seemingly distinct health conditions have, in many cases, a common origin: mother's health during pregnancy and at childbirth. Studies on populations from diverse ethnic origins and countries have consistently found an association between birth weight and diabetes. Malnourished and anemic mothers are more likely to give birth to babies with low birth weight and children with low birth weight are more likely to have diabetes. In 2007, a study by the National Public Health Institute in Helsinki, Finland found that very low birth weight (less than 3 pounds and 5 ounces) adults aged 18 to 27 were almost 20 percent higher on the insulin-resistance index than comparable adults with normal birth weight. The study, published in New England Journal of Medicine, found very low birth weight adults to show several other signs of impaired glucose regulation. The low birth weight group had an almost 10 percent higher two-hour glucose concentration, as determined by an oral glucose tolerance test than the group with normal birth weight and a 15 percent higher fasting insulin concentration. Improvements in the nutritional levels of young women before and during pregnancy can thus go a long way in not only lowering the incidence of malnourishment among their children but also reduce diabetes risk for these children in adulthood. The sheer size and growth of diabetes in urban India is frightening. About half a century ago, prevalence of diabetes was almost negligible in India — one percent or less in major cities. In 2004, prevalence in urban areas averaged more than 16%, according to estimates by Dr. V. Mohan and colleagues. The just released results of phase 1 of the Indian Council of Medical Research — India Diabetes (ICMR-INDIAB) study, however, suggests that diabetes is growing at a much faster rate than was estimated even a year ago. Estimates from this study indicate prevalence of diabetes to be 10.4 per cent in Tamil Nadu, 8.4% in Maharashtra, 5.3% in Jharkhand and 13.6% in Chandigarh. Based on the surveys in these three states and one union territory, covering phase 1 of the study, ICMR-INDIAB has extrapolated that there are 62.4 million persons with diabetes in the country — 12 million more than the estimates in 2009, and 77.2 million with prediabetic condition.

Type 2 diabetes is caused by genetic factors as well as life style factors namely dietary practices and physical inactivity. Scientists have long believed that people of Indian origin are at a high risk of diabetes due to genetic factors. We now see these genetic factors interacting with life style changes resulting for economic prosperity, urbanization, and sedentary lifestyles. Indeed, similar increases in obesity levels were found among emigrant Indian communities who experienced economic prosperity and the associated life style changes earlier than Indians living in India.

What makes the trend in India more worrisome is that it is growing among the young and among populations that fall within the normal weight range, as per the World Health Organization guidelines. In western countries, the average age at onset of type 2 diabetes is typically around 50. The age at onset in India, as in many other Asian countries, is on average about 15 to 20 years less. The ICMR-INDIAB study in fact finds a rising incidence among the 25-34 years age group. Moreover, diabetes appears at a much lower threshold of weight in India than in most western countries. Up until recently, at least in India, diabetes was the disease of the wealthy. This is no longer the case. The recent trend reveals that its prevalence is spreading among the rural middle class and among the urban poor. To some extent, nutritionists believe that, this is due to changes in the quality of grains consumed. Ragi, jowar, bajra, commonly viewed as poor man's grains in India, are richer in health nutrients than rice and wheat; highly polished fine rice is merely starch. The rising incidence of diabetes in the middle of large scale food insecurity and undernourishment makes one thing clear: health issues relating to nutrition are not the same across all groups and all regions, and there could be no single solution that will solve all. A highly inefficient and corrupt public distribution system, for instance, will not solve the problems of hunger, obesity, and diabetes. We need a large scale public health education initiative, at least in urban areas, on healthy nutrition and life styles informing the young benefits of healthy eating and physical exercise. A better regulation of the fast food industry with strict food quality standards is long overdue.

Source: *The Economic Times, 8th October 2011*

Pharma M&As by MNCs to Face Competition Check

The government found a middle ground in the fight between domestic and multinational drug companies although it decided against lowering the foreign direct investment (FDI) permitted in the pharmaceuticals sector. Amid clamor from local pharma firms to cut the cap to 49% in case of M&As and stake acquisitions by global giants, the government settled for a mechanism under which Foreign Investment Promotion Board would vet all proposals for six months. During this period, the Competition Commission of India (CCI) will put in place "regulations for effective oversight on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the sector.

The decision followed deliberations at a meeting convened by Prime Minister Manmohan Singh as there was sharp division between ministries over the issue of regulating the entry of foreign pharma firms in India.

The health ministry and DIPP feared a spate of acquisitions by foreign firms could raise medicine costs and affect domestic manufacturing capacity. In recent years, several home-grown players have been acquired by MNCs including Ranbaxy Laboratories by Daiichi Sankyo of Japan, Shanta Biotech by Sanofi Aventis of France and Piramal Health Care by Abbott Laboratories of the US.

Source: *The Times of India, 11th October 2011*

Vitamin Pills Not Good for Health

People on dietary supplements have higher death rates, says study

Women taking multivitamins don't live longer than those who get their nutrients from food alone, according to a US study that found they in fact appear to have slightly higher death rates. About half of adult US residents take dietary supplements, and the industry now boasts of annual sales as high as $20 billion. Yet research suggests that some of the largely unregulated substances, such as vitamins A and E, could be harmful in high doses. “There is very little evidenceshowing that common dietary supplements would be beneficial in prevention of major diseases,” said Jaakko Mursu of the University of Minnesota in Minneapolis. “Unless you are deficient, there is no reason to take them,” he said. Mursu and his colleagues used data from nearly 39,000 older women who participated in the Iowa Women's Health Study and filled out questionnaires starting in 1986. The survey asked about use of multivitamins, vitamins A, C, D and E as well as beta-carotene, B vitamins and minerals such as calcium, copper, magnesium, selenium and zinc.

During the study, supplements became increasingly popular. Between 1986 and 2004, the proportion of women who said they took one or more jumped from 63% to 85%. Only calcium supplements were linked to a lower risk of death over 19 years of follow-up. That link held up even after considering that women taking supplements had a healthier lifestyle than the rest. By contrast, women taking other supplements did not live longer.

Source: *The Times India, 12th October 2011*

Humble Guava is Healthiest Fruit, Pineapple Least

The humble guava is the healthiest fruit for the human body, while the pineapple is at the bottom of this index. The first-of-its-kind research to evaluate the amount of natural antioxidant levels of 14 fresh fruits commonly consumed in India has come up with surprising revelations. Guava, along with the Indian plum, mango, pomegranate, custard apple and apple offer the highest amount of antioxidants.
The study — conducted by Hyderabad's National Institute of Nutrition — found that pineapple, banana, papaya, water melon and grapes had the least amount of antioxidants. Antioxidants play a crucial role in preventing cellular damage — the common reason for aging, cancer and several degenerative diseases. In a study published in the journal 'Food Research International', lead author Dr. D. Sreeramulu from NIN's endocrinology and metabolism division found that antioxidant activity ranged from as high as 496 mg/100 grams in guava to as low as 22 mg/100g in pineapple. Dr. Sreeramulu told TOI, “The findings came as an eye-opener. We usually believe expensive fruits are the richest source of nutrition. But our extensive research shows that fruits that are rich in antioxidants help scavenge free radicals that destroy tissues.”

Modern lifestyles, he adds, lead to an excess of free radicals. Free radicals are atoms that can start a chain reaction and cause damage when they react with important cellular components such as DNA or cell membrane. Cells may function poorly or die if this occurs. Dr. Sreeramulu said epidemiological studies from other parts of the world indicated that increased consumption of fruits was linked with lower risk of chronic degenerative diseases. Fruits are an important component of Indian diets. Studies show that fruits are rich sources of phenolic compounds and antioxidant activity (AOA).

The study was taken up to determine the anti-oxidant and phenolic content of fresh fruits commonly consumed in India. Current lifestyles cause overproduction of free radicals. Natural

antioxidants protect from oxidative stress and associated diseases, therefore, play an important role in healthcare.

Fruits are important dietary sources of anti-oxidant polyphenols to humans. In recent times, natural antioxidants have attracted considerable interest among nutritionists, food manufacturers and consumers because of their presumed safety and potential therapeutic value," he said.

Three samples of each variety of fresh fruit were purchased, edible portions cut into small pieces and extracted with acidified aqueous methanol. Briefly, edible portions of fresh fruits were directly taken into a polytron homogenizer and extracted. Extraction and analysis of antioxidant activity and total phenolic content was done separately in three market samples. "Dietary polyphenol intakes from fruits and vegetables are known to reduce the risk of coronary heart disease and cancer. The present data will be useful to consumers to plan anti-oxidant rich diets and to the health professionals and nutritionists in estimating the daily intakes of phenolic antioxidants and their impact in health and disease," he added.

Source: *The Times India, 12th October 2011*

Drug Launches Drop in Local Mkt

Fewer original drugs go off Patent and Indian Cos Opt for different biz models.

New brand launches in the local drug market have declined over the last few years, since the number of original drugs going off patent has come down and since Indian companies look at new business models to boost sales and increase profits. A total of 2,184 new brands, including line extension of old brands, hit the retail market in 2010 down 13% from 2,506 in 2007, according to IMS Health data. For the eight-month period ended August 2011, drug makers have launched only 1,014 brands.

According to a senior executive at one of the country's top drugmakers, few original drugs are going off patent globally, so it is only natural that less number of generic brands are being launched. "This is a global trend," he said. Cipla's CFO, S. Radhakrishnan, says the introduction of the product patent regime in 2005 restricted generic drugmakers from selling their version of patented drugs and this is in turn has limited the launch of generic brands. Mr. Radhakrishan said his company follows a dual strategy of leveraging on existing brands as well as launching new ones, and has maintained its annual average launch of 35 new brand introductions. Before 2005, India did not follow a product patent regime and local drug makers could launch generic versions of patented drugs within a few years of their global launch.

But now, domestic companies can launch their versions only after the product patent of the innovator company expires. The life of a product patent is 20 years. Pharma analysts say Indian companies are also going slowly on product launches because they are focusing on innovative models to boost sales. They point out that even though new launches have come down by 13% in the last four years, the domestic market was growing at an annual rate of over 15%. "Some firms are following aggressive pricing strategies and playing the volume game. Others, particularly MNCs such as MSD and Sanofi Aventis are focusing on patient monitoring services to ensure usage of their drugs," said an analyst. According to IMS Health Senior Director (Strategy Planning and Business Development) Kumar Hinduja, most major players including local companies were engaged in intensive brand building strategies. This has resulted in an increase in revenue earned per brand. While the number of new products launched by Indian firms has clearly come down in the last few years, there has been a slight increase in the number of products launched by foreign firms.

Source: *The Economic Times, 12th October 2011*

Stem Cells May Make Transplants History

V. Ayyappan| TNN:-
Gene Therapy is being used to regenerate parts of organs like liver and Kidney.

In the near future, doctors will be able to take a liver out, repair it and put it back even as the patient is on the operating table. This could end the harrowing wait of end-stage liver failure patients for donor organs, as a scientific project by a team in the University of Toronto Transplantation Institute promises. India, where several hospitals do stem cell therapy, may be able to utilize the breakthrough to save its increasing number of liver patients. The big promise comes from tiny stem cells, said Dr. Gary Levy, director, University of Toronto Transplantation Institute, who was in the city for a conference on regenerative medicine. "Growing patches for a lung, kidney or heart, from a patient's own cells may soon be possible. These patches can be used to replace ailing organs," he said. University of Toronto Transplantation Institute is already using gene therapy to regenerate parts of liver by injecting genes as soon as they are harvested. "We are planning to do the same with heart and kidney. Studies have found that human donor lung can be repaired to a large extent by delivering a gene, 1010, to increase oxygen capacity. International studies are on to confirm this," said Dr Levy. "We are able to service only 40% of patients because of shortage of good donor organs. Increasingly, people under 50 need multi organ transplants. About 10 million people die of organ failure across the world every year," Dr. Levy said. The experiment in the university began some years ago, when doctors were trying to repair organs that came as donations from brain dead patients.

Brain death is an irreversible condition when the brain loses control over other vital organs. In more than 90% of the cases a head injury due to accident causes the condition. Such patients are considered clinically dead, but their organs can be used to replace ailing ones in patients whose organs have failed. With the number of patients with heart, lung, kidney, liver and pancreas failure growing, the demand for organs have been increasing globally. But transplant surgeons are forced to give up some organs as they aren't fit for transplant. "If we repair them, we could minimize wastage," Levy said. Another challenge is to ensure that once transplanted, the new organ is not rejected by the body.

During the experiment, doctors stumbled upon another possibility: repairing patient's own organ on the operation table. The transplantation institute at the University of Toronto, he said, was using stem cell therapy to regenerate parts of liver and lungs. For instance, when a lung failure patient is on the operation table, doctors stop the lungs and connect the patient to a machine that 'breathes' for him. Meanwhile, doctors can take out the lungs and inject stem cells that can improve their capacity to absorb oxygen. In many cases, patients have been able to avoid or delay transplants, he said.

The institute is planning to work on heart and kidney. Similar treatments could be used to remove fat from liver. Excess fat in the liver can cause the organ to fail. Many people undergoing transplants are now being given immunosuppressive drugs. Regenerative medicine can be used to reduce their requirement, Dr Levy said. "It's heralding a whole new era of intelligent and personalized therapy. We can re-educate the immune system. If we manage to do that with organ transplant, we would open pathways that will be useful to treat cancer, multiple sclerosis and other viral diseases," he said.

Source: *The Times India, 12th October 2011*

Biotech Firms Gamble on Patent Regime Shift

Billions of dollars worth Pharma products will go off – Patent from 2013, opening new market for domestic biotechnology entrepreneurs, writes Biswarup Goopu.

Indian biotechnology entrepreneurs are betting big on a change in patent regime, which is expected to see over $70 billion worth of global pharmaceutical products going off-patent 2013 onwards. The stuttering sector is desperate to access new markets, as they seek to shore up waning investor interest. Since 2008, the Indian biotechnology sector has seen only a handful of investments by risk capital players, with a maximum of $12 million being invested in 2010 across four deals, according to Venture Intelligence, a research service focused on private equity and mergers and acquisitions. The consensus has been that the industry, which promised much, has delivered little. This could soon change, as a number of blockbuster drugs worth billions are set to lose their patent protection over the next two years. Indian biotechnology companies such as Aizant Drug Research Solutions, Mitra Biotech and Richcore Life Sciences are looking to exploit lucrative opportunities in areas of new drug development, bio-generics and clinical research outsourcing. "The domestic biotech companies have to tap into the US, European and Japanese markets. 2013-14 can be the new inflection point if they can utilize their low cost manufacturing models and research and development expertise to cash in on the opportunities that could come their way," said Ajit Mahadevan, partner, Life formulations, to the US Food and Drug Agency," pointed out Mukul Gulati, Managing Director of private equity fund Zephyr Peacock India Management. Also hoping to capture a significant portion of the estimated $23-billion global clinical research outsourcing market is Mitra Biotech, with their analytical diagnostic platform focused on personalised cancer treatment. "Our core tool Oncoprint, a diagnostic application, helps patients by picking the right drug combination and can be used in clinical trial developments as well. Separately, we are also looking at drugs that have failed clinical trials," said Mallikarjun Sundaram, co-founder and chief executive, Mitra Biotech.

In April 2010, the company – spun off from the Massachussets Institute of Technology – saw a first round investment of about $2-3 million from Accel Partners and KITVEN, a Karnataka-government initiated venture capital fund. "We plan on going for another round of funding soon, but funding, as a rule, is difficult in India, largely because of the risks involved with the industry," Sundaram said. But the opportunities are not limited to the pharmaceutical end only. The Bangalore-based start-up, which reported revenue of $3 million last fiscal, plans to license its technology to other countries, and expects to have revenues of $20 million at the end of the current financial year. "It is a $25-billion market globally," said Richcore's founder Subramani Ramachandrappa. He added that while companies like Novozymes and Genencore were already producing enzymes and ethanol, Richcore has developed new applications of enzymes. "We use natural mutation and genetic modification in microbes to produce the enzymes suitable to solve problems. As a small company, the only way we could survive was by doing something new," said Ramachandrappa. But it's the lack of capital that continues to be a worry.

In a recently released report on the biotechnology sector, global consultancy Ernst&Young pointed out that the Indian biotech industry was largely dependent on government funding, with only a handful of venture capital funds focusing on this industry and an almost negligible angel investment flowing in. "In India, there are only a handful of investors ready to put money in drug discovery. There are serious challenges in raising funds, especially early-stage capital. The private equity players are more interested in less-risky propositions," said Mohit Mathur, director, Neev Advisors, a boutique life-sciences and healthcare-focused advisory firm.

Source: *The Economic Times, 14th October 2011*

Spare a Thought for Vaccine Policies

K. S Jacob:-

All stakeholders — government, academia, industry, public health systems, health providers and the community — need to be engaged to formulate rational and relevant vaccine policies.

Vaccines are considered the greatest of public health strategies to prevent disease. The marked reduction of many infectious diseases from regions with good public health programmes argued the case. The eradication of smallpox was a triumph in this area. Nevertheless, there are many ongoing debates on vaccines and their use in India.

Public concern about vaccines dates back to the introduction of vaccine legislation in the mid-1800s. There are recent public apprehensions about vaccines; those who voice them are not against vaccination per se. Such concerns arise because vaccines differ from other medical interventions, as it involves healthy individuals being immunized to achieve a protective public health benefit. The public, empowered by the internet and sophisticated social media, want answers to their concerns. Their questions include safety, schedules, affordability, relevance, benefits, risks and funding. Several factors drive public anxiety: poor immunization coverage of established inexpensive vaccines, push for newer expensive products, perceptions about the vaccine industry, conflicts of interest among decision makers, perceived pressures on institutions responsible for public policy, skepticism about scientific truths and perceived risks.

Pr Disasters

There have been several recent public-relations disasters for academia and the vaccine industry. A scientific publication, later discredited and retracted, documenting a link between the measles, mumps and rubella vaccine and autism tapped into a reservoir of public paranoia. The failure of the predicted swine flu pandemic to materialize combined with profits for vaccine and pharmaceutical industries, increased public mistrust of health authorities.

Many factors drive public perceptions. While scientific evidence and economic analysis have a major impact, a complex mix of psychological, socio-cultural and political factors also drives public discernment.

The Scene In India

Vaccination programmes and policies in India have to contend with many complex issues.

Adverse effects: Vaccines are very safe and many studies have documented that their adverse effects are very rare or very minor. However, poor monitoring systems in our country do not allow for systematic surveillance. Adverse events after immunization are strong factors that prompt rumors. Consequent public concern undermines the voluntary nature of vaccination programmes. Although the government does have some information, the lack of systematic data collection does not allow for robust defense of the programme.

Deaths: Sudden deaths after immunization are not unheard of and occur very, very rarely. However, the system of investigation into such tragedies is non-uniform and many enquiries tend to absolve the vaccine and procedures. The denial of problems and post-hoc compensation for such tragedies put the whole programme at risk. Drastic changes in procedures in response to post-vaccination deaths, as in Tamil Nadu, compound the problems. The insistence that all children be brought to primary health centres for immunization resulted in markedly reduced coverage. Rumor has it that an error by an individual resulted in far-reaching changes in policy and practice.

Vaccine supply: The sudden forced stoppage of essential vaccine production by government manufacturing facilities resulted in massive disruption to immunization schedules and programmes. Squabbling among politicians, civil servants and experts did not instill public confidence. The subsequent judicial intervention, months later, restored manufacturing at these facilities but the disaster resulted in public distrust.

Private players: Liberalization of the Indian economy has increased the number of private players in the vaccine industry. Many private players made a killing when government manufacturing was stopped. The government's neo-liberal agenda and the captive market for vaccines present an obvious business opportunity for exploitation. Consequently, the right-to-health-care argument has found enthusiastic support from the vaccine industry. The recent attempts to argue for expensive vaccines with limited protection (e.g. pneumococcal vaccine) for uncommon disorders fuelled speculation about the role of big business in pushing commercial interests.

International involvement: Many international financial institutions are more than willing to fund vaccine programmes. However, their focus tends to be on the newer and more expensive vaccines and for pre-production and monopolistic pricing arrangements. The high prices, often out of reach of poorer nations, make such ventures suspect.

Failed pandemic: The failure of the swine flu pandemic to materialize, after the initial hype and scare, played into the hands of the vaccine and pharmaceutical industry, which bagged massive contracts. While the post-mortem of the decision making process exonerated international health agencies, procedural lapses like failure to publically declare conflicts of interests among decision makers, resulted in adverse publicity and increased skepticism of health authorities.

Unethical trials: Deaths of young tribal girls enrolled in the human papillomavirus (HPV) vaccine trial in Andhra Pradesh resulted in suspension of the programme. Issues related to conflicts of interests and unethical nature of informed consent and recruitment procedures highlighted a callous approach of industry, non-governmental organisations and health authorities.

International disagreements: This add to public concerns. These include the American recommendation for the removal of thiomersal (a chemical to prevent biological contamination) from childhood vaccines, the French decision to withdraw the hepatitis B vaccine from school programmes, and the temporary Japanese suspension of the Haemophilus influenza B vaccine. The unwarranted controversies related to the tetanus vaccine and sterilization in Mexico and the polio vaccine and HIV in Nigeria did not help the cause.

New reality: Deception employed to wage war (in Iraq), massive corruption within governments and collusion between business, politicians and bureaucrats has resulted in public suspicion of authority. Dialogue among consumers, via the internet, has facilitated the questioning of advice from traditional establishments. Media attempts for balanced coverage also allow highlighting of extreme views. Social media have allowed for the building of large virtual coalitions, which create a "social amplification of risk." Vaccines have been so successful that low statistical risk takes on a different meaning. The internet, a vast archive of misinformation, mandates even greater need for public health education.
Polarized positions: Public concerns have resulted in public interest litigation and the use of the Right to Information Act to elicit information. The polarized positions of those for and against the new vaccines are obvious.

The vaccine industry and health authorities dismiss social context, economic concerns, human rights and political struggles as inconsequential. Scientists cite complex technical arguments, often based on non-Indian data, in support of new

vaccines. They imply that all those who raise any objections are part of the anti-vaccine lobby. On the other hand, those against such initiatives emphasize the lack of good Indian data, selective citation of evidence and cast aspersions about business interests. The experts and the community, by their particular locations, differ on experience, perceptions, attitudes, and challenges. The absence, in the public domain, of information, evidence and policies, and the lack of transparency in decision making make it difficult for a rational and robust defense of either stand.

Moving Forward

Traditional hierarchies, accepted for centuries, are being challenged in this new context and age. Increased cynicism and suspicion of authority is here to stay. Consequently, health establishments cannot dictate; they need to negotiate with communities and convince them of the need, rationale, efficacy and cost benefit of newer vaccine policies.

India can no longer ignore the elephant in the room, the limited data and the poor systems of information gathering, which do not allow for monitoring, generating evidence and rational policies. There is an urgent need to establish sentinel centres in order to determine the prevalence of the diseases and conduct large-scale trials to assess impact. Even though the vaccines may be efficacious, a detailed cost-benefit analysis from a public health perspective is mandatory for policy-making.

The current wave of public skepticism seen in many parts of the world has been described as a "crisis of confidence." It mandates the restoration of public trust, essential for sustained vaccine coverage. Vaccine interventions and policies in the current socio-economic and political climate require much more than research evidence for implementation. Engagement with stakeholders and local politics, transparency in decision making, discussing uncertainties about risks and enhancing local ownership are crucial. Until then, arguments, based on polarized positions will continue with each side accusing the other of either obstructing progress or of making sound business investments at the cost of the nation's public health. There is a need for rigorous research to establish need, effectiveness and cost-benefit and for greater efforts at understanding factors that determine public trust. National policies need to be relevant, valid, accountable and participatory. Communication, dialogue and engagement with all stakeholders are crucial to building public trust, mandatory for successful vaccine programmes, and call for a revolution in policy-making.

Source: *The Hindu, 17th October 2011*

(Professor K.S. Jacob is on the faculty of the Christian Medical College, Vellore. The views expressed in this article are personal.)

Polio Vaccine Absolutely Safe, Don't Believe Rumours

Shastry. V. Mallady

The State government is adopting a comprehensive strategy to keep the State polio-free and ensure that all children are covered under the polio immunization.

Also, the Health Department officials have stepped up public awareness campaign to convey that the polio drops are safe and that parents should not have any sort of doubts or fear about the safety of polio vaccine.

Multiple strategies

"We are making sure there is no import of polio

case through migrant workers. Districts where there is large migrant population such as Chennai, Kancheepuram and Coimbatore are kept under strict surveillance. Besides, the routine polio immunization too has been strengthened," she said. Dr. Vanaja was in the city to make a presentation on "Tamilnadu's Plan of Action" for polio eradication at the Polio plus Planning and Orientation Meeting jointly organised by the Rotary District 3000 and Rotary Club of Madurai West here on Sunday.

Satisfactory

While expressing satisfaction that not a single polio case was reported in Tamil Nadu in the past seven years, the Joint Director cautioned that the Health Department and other partners in polio eradication drive should not be complacent at any stage.

"We must sustain that zero polio status for ever. To achieve that, the active participation of public is essential and every child must get the oral polio vaccine. The polio vaccine is supplied by the Government of India only after lots of checks and it is absolutely safe," Dr. Vanaja said.

She said the State Health Department has now roped in Village Health Nurses for the polio immunization activity in order to make sure that every child is getting the vaccine.

Referring to the rumors spread in the State about children dying after the polio drops were given to them a few years ago, the Joint Director said parents should not believe false information spread about vaccine safety.

Rotary's support

P. Sambasiva Rao, Member, National Polio plus Committee, had highlighted the extensive funding support made by Rotary Clubs across the country for polio eradication mission.

Y. Kumaran, Rotary District Governor Elect, Santhosh Rajagopal, Surveillance Officer, World Health Organisation and K.R. Raja Govindasamy, president, Rotary Club of Madurai West, were among those who spoke at the orientation meeting for health department staff and Rotary Club members.

Source: *The Hindu, 17th October 2011*

Who Will Pay for Malaria Vaccine?

The trials look promising, but the next challenge is to keep the costs down

Malaria is a mass killer, taking just under 800,000 lives a year. Most of them are babies and children under five. A significant number are pregnant women. It is an entirely preventable disease, caused by a parasite transmitted by mosquito bite, but the millions who live under its curse are too poor and have too few options to be able to avoid it.

The malaria vaccine [See: "Malaria vaccine partly effective" — 'Science & Technology' page, October 20, 2011] that now appears to be within reach, following successful large-scale trials in seven African countries, is a potential game changer for the rural villagers whose children are the main victims of this ancient disease, which was named "mal'aria" for the bad air mediaeval Italians thought caused it.

Early results from 6,000 babies aged 5-17 months show that their risk of malaria was reduced by slightly more than half (56 per cent) and their chance of severe malaria — the kind that affects the brain, kidneys and blood and often kills — by slightly less than half (47 per cent).

Malaria is so common in sub-Saharan Africa that families think any fever in a baby must be the killer disease. Too often it is, and the hospitals are full of

listless babies with vacant eyes on drips.

Vast numbers of bed nets impregnated with insecticide have been provided by donors and distributed in malaria-endemic regions. New drugs — compounds involving artemisinin [See: Editorial page, The Hindu, October 5, 2011] — have been developed and widely distributed to replace older antimalarials, which have been failing as the parasite develops resistance to them.

Mortality rate down

Malaria deaths have come down from more than a million to an estimated 780,000 a year, according to the latest report from the Roll Back Malaria partnership of the World Health Organisation (WHO). Three countries were certified malaria-free in the past four years, and nine more are preparing to move towards elimination — but that is out of 108 where the disease is endemic.

Since bed nets are not always effective and drugs can become ineffective, a vaccine could massively improve children's chances.

While researchers started work on a potential Aids vaccine with extraordinary and, as it turned out, misplaced optimism, many in the scientific community thought a malaria vaccine was a non-starter. Nobody had ever made a vaccine against a parasite-borne disease.

Twenty-five years on, a clutch of indomitable scientists — veterans such as Joe Cohen, who has been on the case for the past 23 years — has proved the sceptics wrong. According to Andrew Witty, chief executive of GlaxoSmithKline, the British company that has developed and trialled the vaccine, there were tears among the team when the results of the large-scale trial results came out. “It was the emotion of what they had achieved,” said Witty. “The first vaccine against a parasite-borne infection. They were overwhelmed.” The results show conclusively that it is possible to prevent many cases of malaria in babies aged 5-17 months. Most of these children still got malaria, but less frequently and less severely. There were 750 cases for every 1,000 vaccinated children over a year, compared with 1,500 cases for 1,000 children (as one child can have more than one bout of the disease) among those who were given dummy injections.

That could make a big difference in sub-Saharan Africa. There are 200m cases of malaria every year. Many children are damaged — sometimes brain-damaged — by it. Even stopping half of those cases would save millions of lives over the long term. But there is a way to go yet, with more results from the trial to come, and many uncertainties, including how much this vaccine will cost and who will be persuaded to pay.

Trial in seven countries

The trial is continuing in seven countries: Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania. It is big: there are 15,460 babies and infants involved. The data published so far in the New England Journal of Medicine concerns 6,000 of the older babies, those aged 5 to 17 months. Next year, results are expected for newborns, which are crucial, because the three-dose vaccine, which needs cold storage, must be incorporated into the routine infant vaccination schedule. All the signs are, though, that the response in newborns will be similar.

A bigger question is over the duration of the protection, which appears to have dropped from 47 per cent to 35 per cent for cases of severe malaria after 22 months. Some of the babies will be given a booster, to see whether this helps. While most side-effects were similar in children given the vaccine and given dummy jabs, there were significantly more with meningitis among those given the vaccine. “There seems to be no plausible explanation for this and it may well turn out to be a chance finding, but it cannot be ignored,” wrote malaria expert Prof Nick White in a commentary otherwise warmly welcoming the vaccine.

In three years' time, when the final results are in and the WHO has recommended its use, the scientists may hit the biggest stumbling block of all: money to roll it out. At a press conference to discuss the results, Dr. Regina Rabinovitch, director for infectious diseases at the global health programme of the Bill and Melinda Gates Foundation, was asked whether they would fund it. They would want to look at the data on efficacy, duration and safety in 2014, she said. "Would I prefer to see a 100 per cent vaccine? Certainly," she added.

Price will be a critical factor. Witty says they will do everything they can to get it down. He is prepared to offer licenses to get the vaccine produced cheaply in India or in Africa itself.

"I have got every confidence that we can get this price to a level that makes it very viable for donors to consider," he said. "I don't want people to think this is an alternative to bed nets. This is about doing all we can to shut the door on malaria." He recalls the hospital wards he has seen in Africa, full of malaria cases: "If you could take that burden away, imagine what the health capacity would be."

(Sarah Boseley is the Guardian's Health Editor.)

Source: *The Hindu, 20th October 2011*

EU Austerity Hits Desi Generic Cos
Govts Have Cut Drug Prices By 20-30% As A Measure To Check Crisis

Economic woes and austerity measures taken by governments across Europe have resulted in steep price cuts on generic and innovator drug companies, which are likely to impact domestic generic companies. Domestic majors like Ranbaxy, Dr Reddy's and Torrent have a reasonably significant exposure to these markets. Europe contributes around 15-20% of the top line of most companies, while Germany is the most important market for domestic generic firms.

"The price cuts witnessed across Western Europe is definitely a cause for concern for companies having a sizeable presence," Glenmark chairman and MD Glenn Saldanha told TOI. Also, since economic growth is subdued across these countries, it is putting further pressure on pharma companies operating in this region, and going forward, the situation is likely to get worse.

Though the European governments had imposed price cuts over the last couple of years, these have now become steep. Also, countries including Spain and Portugal have announced larger cuts, ranging between 20-30% on generic drug players, as against innovator companies.

To make matters worse, with certain European economies tethering on bankruptcy, their governments have also slashed healthcare budgets, putting further pricing pressure on generic companies. The share of healthcare expenditure in GDP is high in several European countries and a significant part of this is funded by governments. These persistent actions make western Europe an increasingly difficult terrain for pharma companies, putting a strain on their margins and revenues.

Domestic pharma companies generate revenues ranging Rs 180-Rs 1240 crore from European countries. The exposure is particularly high for some mid-caps such as IPCA and Torrent, which derive almost a fifth of their revenue from their European business. Dr Reddy's and Ranbaxy, which are more diversified globally than their peers, also draw around 11-14% of their overall revenue from these geographies.

Ranbaxy, which derives around Rs 1200 crore from

the geography, has set up a manufacturing facility in Romania which serves as a hub for EU, while Glenmark has a plant in Czech. Others, Dr Reddy's and Torrent derive about 65-71% of Europe revenue from Germany, owing to their respective acquisitions of Betapharm and Heumann Pharma, and hence they would be impacted significantly, analysts added. Cipla, Lupin and Cadila also have sizeable revenue flowing from the region. Saldanha adds: "Glenmark's western European business was around $12 million (Rs 50 crore) last year. We still feel that this business is well positioned to grown in excess of 50% in this year too. Presently we have not felt the pressure as we have focused on niche product categories, and also considering that we have a small base". Europe contributes around 6% to Glenmark's overall sales (Rs 3000 crore), with Czech and UK being major markets.

Source: *The Times of India, 21st October 2011*

SC Dismisses DCGI Plea Against HC Order

The Supreme Court has dismissed a special leave petition filed on behalf of Dr. Surinder Singh, Drugs Controller General of India (DCGI), against an earlier order of the Madras high court faulting the extension of tenure granted to him. The matter, which came up for hearing before a bench of Justices D K Jain, Anil R Dave and Sudhansu Jyoti Mukhopadhaya, was dismissed as the bench concluded that no ground was made out for its interference.

Appointed on deputation on February 1, 2008, Dr Singh held the post for three years and was granted a further extension on June 8, 2011. This would have enabled him to stay in service for nine more months to March 31, 2012. However, a petition alleging irregularities in his appointment was filed by Mr. Ramalingasamy, a retired official from the state drugs control department, before the Madras high court.

The plea sought for an inquiry into Dr Singh's appointment and for the framing of rules to guide recruitment of candidates for the post. Mr. Ramalingasamy said that while Dr. Singh headed the Central Research Institute and Central Drugs Laboratory at Kasauli during his previous stint, the license granted to the institutes was suspended as they had failed to comply with good manufacturing practices. Yet Dr. Singh was appointed as DCGI above several other persons who were more qualified, the petition added. When the matter came up for hearing at the Madras HC in July, 2011, advocate P. T. Asha, counsel for petitioner, contended that he could not be granted an extension when a plea challenging his appointment was pending before the court. The HC stayed the extension at the time.

At the next hearing in August, additional solicitor general of India Mohan Parasaran submitted that recruitment rules for the post had been framed and notified on June 14, 2011.

However, the first bench of Chief Justice M. Y. Eqbal and Justice T. S. Sivagnanam, noted that the order of extension was passed even before the recruitment rules were notified. The judges observed that no record was placed before the court to show the manner in which such relaxation was granted and what weighed with the department of personnel and training to grant such a relaxation in his favour.

Source: *The Times of India 24th October 2011.*

WONDER DRUG?

Aspirin Drastically Brings Down Rate of Colorectal Cancer: Study

Aspirin, the drug used by millions of people to protect their heart, has been found to drastically reduce colorectal cancer rates among those, who have an increased hereditary risk. The first randomized controlled trial (RCT) to assess aspirin's effect on cancer prevention has shown a reduction in colorectal cancer incidence of over 60% in patients at genetically increased risk who use aspirin for long. The findings of the study, involving 43 centres in 16 countries that followed about 1,000 patients in some cases for over 10 years, have been published in "The Lancet" on Friday.

"The case for chemoprevention using aspirin in these patients is now clear," says chief author of the study Professor Sir John Burn, Newcastle University, the UK. The authors say: "600 mg aspirin per day for a mean of 25 months substantially reduced cancer incidence after 55.7 months in carriers of hereditary colorectal cancer.

Further studies are needed to establish the optimum dose and duration of aspirin treatment. The case for prescription of aspirin to this high-risk group is clear." All patients were carriers of Lynch Syndrome, a genetic anomaly that predisposes a person to developing colorectal cancer and a range of other solid organ cancers. For the study — conducted between 1999 and 2005 — 861 people began either taking two aspirins (600 mg) every day for at least two years (434 patients) or a placebo (427 patients).

The first analysis of the trial data in 2007 showed no difference in colorectal cancer incidence between those who had taken aspirin and those who did not. However, by 2010, there had been 19 new colorectal cancers among those who had received aspirin, and 34 among those on placebo — those in the aspirin group had an overall 44% reduced incidence of colorectal cancer. A further analysis focused on the patients who took aspirin for at least two years (about 60% of the total), showed that its effects were even more pronounced: A 63% reduced incidence of colorectal cancer was observed with 23 bowel cancers in the placebo group, but only 10 in the aspirin group. The effect came to light five years after patients starting taking aspirin. It was found that about 30% of the patients taking placebo had developed cancer as compared to about 15% of those popping aspirin.

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

Misleading Drug ads Under Lens

Tall claims made by drug advertisements in India are under scrutiny. The Drug Controller General of India (DCGI) has called all state drug controllers and the Indian Medical Association (IMA) to address this "serious menace of misleading medical ads" in the next Drug Consultative Committee (DCC) meeting to be held on November 14.

The DCGI intends to discuss ways to curb ads that make unsubstantiated claims that take "the gullible public for a ride". Union health ministry officials said such ads could prove lethal, if patients take drugs being influenced by publicity campaign.

"We will need the support of doctors to curb these misleading ads. Hence, IMA representatives have been invited to the next DCC meeting," a ministry official said. A study recently published in the "Indian Journal of Medical Research" confirms the dangerous trend of unsubstantiated claims made by these ads. The study — supported and unsupported Claims in Medicinal Drug advertisements in Indian Medical journals — conducted by the National Institute of Pharmaceutical Education and

Research assessed supported and unsupported claims in 292 and 102 medicinal ads, respectively, across 15 Indian medical journals published in 2009.

None of the ads satisfied all the World Health Organization's (WHO) criteria. Safe prescribing information on major adverse drug reactions and warnings were provided in only 19 advertisements. Of the 292 drug claims, 80 (27%) were supported with references, and among them only seven (9%) claims were unambiguous. Superlatives like "tested", "trusted", "guaranteed success" and "matchless safety" were used without evidence to substantiate such claims. The study said "stronger enforcement mechanisms are necessary to ensure reliable drug information in pharmaceutical advertisements." WHO's a norm for medicinal drug promotion says: The text should be legible, ads that make a claim should at least contain summary scientific information and names of active ingredients using either international non-proprietary names or the approved generic name of the drug should be made.

Ads should include the brand name, content of active ingredients per dosage form or regimen, name of other ingredients known to cause problems, approved therapeutic uses, dosage form or regimen, side-effects and major adverse drug reactions, precautions and warnings, name and address of manufacturer or distributor and reference to scientific literature as appropriate. "None of the advertisements satisfied all the ethical criteria set by WHO. Safe prescribing information was given less importance. Only 19 of the 102 advertisements provided safe prescribing information such as on side-effects, major adverse drug reactions, precautions, contraindications and warnings. Only 16 gave information on major interactions," the study said.

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

New Drug Pricing Policy will Hamper Industry's Growth, Complain Drugmakers

The new pharmaceutical pricing policy proposed by the chemicals and fertilizers ministry last week will create distortions in the market and hamper the industry's growth, some drugmakers and regulatory experts have claimed.

Under the National Pharmaceutical Pricing Policy, 2011, proposed by the Department of Pharmaceuticals (DoP), the government will fix and regulate prices of all 348 essential drugs and their combinations – which will cover 60% of drugs sold in the country.

The policy also proposes a shift from fixing the ceiling price based on cost of production to the reference pricing method. Critics of the new policy, comments on which have been invited till November-end, say the policy will favour foreign drugmakers and big Indian multinationals. Lobby group Indian Pharmaceutical Alliance (IPA), which represents big Indian companies, said the policy seems to "have ignored the need for ensuring long-term availability in favour of short-term benefit of ensuring access"

The government has arbitrarily extended the scope of price control by extending it to combinations against the specified strengths and dosage finalised by an expert committee nominated by the health ministry, D G Shah, secretary general of the association, said. The draft policy also does not address the need to promote self-reliance and the issue of India's growing dependence on imports of raw materials and intermediates, critics said.

The founder and chief executive of a leading local vaccine maker said the prices of medicines in the country are already the lowest in the world. Many

drugs sold by foreign MNCs remain outside price control and they can stop selling the ones that are unprofitable, he said.

"There is, however, no choice for Indian drugmakers whose key market remains India," he said. Such stakeholders are expected to share their views before the DoP's deadline ends. Some experts have questioned the basic premise of fixing the ceiling price on the average price of three most-sold brands by value, particularly when the most-sold brands are the expensive ones of foreign MNCs and big Indian players. "Why not the average price of three cheapest brands?

Source: *The Economic Times, 31st October 2011*

Torrent Pharmaceuticals Likely to Outperform Large-cap Peers, Good for Long-Term Bet

Of late, Ahmedabad-based Torrent Pharmaceuticals has found favour among analysts due to good performance on the operational front. This mid-cap pharma company is on a strong growth trajectory and is likely to outperform many of its large-cap peers. It boasts a formidable presence in the Indian pharmaceutical market with high capabilities in the cardiovascular and central nervous system and chronic ailment segments. Overseas business to drive growth: Rapid growth in Torrent's international business is driving the company's performance. For the September quarter of 2011-12, its export formulations business rose by 32.5% compared with the same period last year, far ahead of the estimates.

This growth was clocked across geographies (US, Brazil and Germany), aided by new product launches and focus on acute ailments. The company plans to launch 3-4 new products in Brazil and the US in the second half of 2011-12, which adds to its earnings visibility. Its tie-ups with AstraZeneca and two other MNCs for supply of generic products will also contribute to the top line growth. This rise in the overseas markets is expected to help it deliver a robust performance over the coming period, even as the domestic business is undergoing a slowdown.

The domestic formulations space saw a muted growth of 7% in the second quarter due to the lower off-take and increased competition in the gastro-intestinal therapeutic segment. However, the management has expressed confidence that the domestic business will see a rebound due to new product launches and improving productivity of the sales force.

Margins to remain on a strong footing: Torrent has shown an improvement in its operating margins after achieving better control over R&D spends and driven by higher dollar realizations. For the September quarter, the company's EBITDA margins stood at a healthy 20.6% propped up partly by the rupee depreciation. As its US business is likely to break even in 2012-13 and due to its operating leverage from the new Sikkim plant (capacity utilisation to improve from current levels) its margins will receive a further boost.

Low valuation attracts re-rating: Several analysts have revised the company earnings estimates upwards and re-rated the stock due to its stellar performance in overseas business and improving profitability. The relatively low valuation (it is trading at nearly 30% discount to its large-cap peers) also makes this stock an attractive proposition. Apart from this, a consistently high return on equity (higher than 25%) as well as a healthy balance sheet (strong cash flow and low debt) makes this company a good long-term bet.

Selection methodology: We pick up the stock that has shown the maximum increase in consensus rating by analysts in the past month. It is arrived at by averaging all analyst recommendations after

attributing weight ages to each of them—5 for strong buy, 4 for buy, 3 for hold, 2 for sell and 1 for strong sell.

An improvement in consensus rating indicates that analysts are bullish on the stock. To make sure that we pick only companies with decent analyst coverage, this search is restricted to stocks that have been covered by at least 10 analysts.

Source: *The Economic Times Wealth, 31st October 2011*

Draft Pharma Policy Unlikely to have Major Impact on Drug cos

The impact of draft pharmaceutical policy—which proposes price control on nearly 350 essential medicines—on drug companies may be minimal. This is contrary to popular perception that pharma companies would be badly hit. In fact, the impact of proposed price reduction is expected to be a little over 2% of the total Rs 58,000 crore pharma markets, initial estimates suggest.

Back-of-the-envelope calculations suggest that price control on national list of essential medicines will have an impact of around Rs 1,100-1,200 crore on companies, sources said. Earlier view was that the policy may cause significant losses to companies with the price control being extended on the entire national list. Large companies and multinationals may take a 3-4% hit on their sales since they have premium priced products, sources say.

Industry will heave a sigh of relief as the impact is not likely to be as significant as feared, the sources said, adding that a clearer picture will emerge over the next few days. With the inclusion of the national list, the proposed policy covers around Rs 30,000 crore of the overall industry. According to an analysis—by market consultancy AIOCD—of the five largest selling molecules (value terms) which cover around 14% of the market, their inclusion on the national list would result in a loss of around Rs. 160-180 crore.

The top five molecules analysed include mostly antibiotics—Amoxycillin and clavulanic acid (combination drug), cefixime, atorvastatin, ceftriaxone and azithromycin. The largest selling drug, a combination of Amoxycillin and clavulanic, manufactured by Glaxo, Alkem and Mankind, has a total market size of Rs 970 crore (including all strengths). Among these, Glaxo and Alkem would be impacted by price control.

According to the policy, the ceiling price would be fixed on the basis of Weighted Average Price (WAP) of the top three brands by value (moving annual total value). Manufacturers would be free to fix any price for their products equal to or below the ceiling price. The ceiling prices would be revised annually up to the limit of the change in the Wholesale Price Index for manufactured goods, as notified by the Department of Industrial Policy and Promotion.

Also, drugs under existing DPCO'1995 will have a constant price for next two years, after which they will come under the new policy, including annual revision as per WPI.

Source: *The Times of India, 31st October 2011*

மருந்து சோதனை கூடங்களை ஆய்வு செய்ய நவம்பர் 1ல் பார்லிமென்ட் குழு தமிழகம் வருகை

தமிழகத்தில், அரசு சார்பில் இயங்கி வரும் தடுப்பூசி ஆய்வுக் கூடங்கள் மற்றும் மருந்து சோதனைக் கூடங்களை ஆய்வு செய்ய, நவ., 1ம் தேதி, பார்லிமென்ட் குழு சென்னை வருகிறது. ராஜ்யசபா உறுப்பினர் பிரஜேஷ் பதக் தலைமையில், 31பேர் இக்குழுவில் இடம் பெற்றுள்ளனர்,

வரும் நவ., 2ம் தேதி, சென்னை கிண்டியில் உள்ள தடுப்பூசி ஆய்வுக்கூடம், அதைத் தொடர்ந்து சென்னை புறநகர் பகுதிகளில் உள்ள மருந்து சோதனைக் கூடங்களில், இக்குழு ஆய்வு மேற்கொள்ளும். பின், நீலகிரி மாவட்டம் குன்னூரில் உள்ள பாஸ்டர் தடுப்பூசி உற்பத்தி மையத்தையும் இக்குழு ஆய்வு செய்ய உள்ளது.

தமிழக அரசின் சார்பில் செயல்படுத்தப்படும், தேசிய சுகாதாரத் திட்டங்களையும், தேசிய சுகாதாரத் திட்டங்களையும், இக்குழு பார்வையிட்டு ஆய்வு செய்யும்

3 இடங்களில் சொந்த கட்டடம்: தமிழ்நாடு மருந்து கட்டுப்பாடு இயக்கக் அலுவலகங்களுக்கு, சொந்த கட்டடம் வேண்டும் என்ற கோரிக்கையை அரசு ஏற்று, முதல் கட்டமாக, செங்கல்பட்டு, விழுப்புரம், கன்னியாகுமரி மாவட்டங்களில் மருந்து கட்டுப்பாட்டு அலுவலகங்களுக்கு, சொந்த கட்டடங்களை ஒதுக்க முடிவு செய்யப்பட்டுள்ளகு. அங்குள்ள மருத்துவக் கல்லூரி வளாகங்களில், கட்டட வசதி செய்து தர, அரசு உத்தரவிட்டுள்ளது.

கட்டணம் நிர்ணயம்: வெளிநாடுகளுக்கு ஏற்றுமதி செய்வதற்கு, மருந்து கட்டுப்பாடு இயக்ககம் அளிக்கும் அனுமதி சான்றுகளுக்கு, இப்போது கட்டணம் நிர்ணயிக்கப்பட்டுள்ளது. இதற்கு முன், இச்சான்றுகளுக்கு கட்டணம் வசூலிக்கப்படுவதில்லை. இப்போது, தாராள விற்பனை தகுதிச் சான்றுக்கு 100 ரூபாயும், சிறந்த தயாரிப்புக்கான தரச் சான்றுக்கு 300 ரூபாயும் கட்டணம் நிர்ணயிக்கப்பட்டு, வசூலிக்கப்படுகிறது.

தகவல்: தினமலர், 28 அக்டோபர் 2011.

குன்னூர் பாஸ்டியர் நிறுவனத்தில் பார்லிமென்ட் நிலைக்குழு ஆய்வு

குன்னூர் பாஸ்டியர் நிறுவனத்தில், பார்லிமென்ட் நிலைக்குழுவினர் ஆய்வு செய்தனர்.

வெறிநாய் கடியால் ஏற்படும் ரேபீஸ் நோய் தடுப்பு மருந்து, முத்தடுப்பூசி மருந்து (கக்குவான், தொண்டை அடைப்பான், ரணஜன்னி) ஆகியவை குன்னூர் பாஸ்டியர் ஆய்வகத்தில் தயாரிக்கப்பட்டு வந்தது.

இது, மத்திய அரசின் கட்டுப்பாட்டில் உள்ளது. உலக சுகாதார மைய பரிந்துரையை பின்பற்றத் தவறியதால், நிறுவனத்தில் மருந்து உற்பத்தி செய்ய கடந்த 2007ல் மத்திய சுகாதாரத் துறை தற்காலிக தடை விதித்தது.

இந்த தடையுத்தரவு கடந்தாண்டு நீக்கப்பட்டு, உலக சுகாதார மையத்தின் பரிந்துரைக்கேற்ப, முத்தடுப்பூசி மருந்து தயாரிக்க அனுமதி வழங்கப்பட்டது. கடந்த ஓராண்டாக மருந்து உற்பத்தி செய்யும் பணி நடந்து வருகிறது.

இதற்கிடையில், உலக சுகாதார நிறுவனத்தின் பரிந்துரைக்கேற்ப புதிய தொழில்நுட்ப ஆய்வுக்கூடம் உட்பட கட்டமைப்பு வசதிகள் மாற்றியமைக்கப்பட்டு வருகின்றன.

அடுத்தாண்டுக்குள் மருந்து உற்பத்தி நிறைவு பெற்று, மத்திய அரசின் ஒப்புதலுக்கு அனுப்பி வைக்கப்படும் என கூறப்பட்டது.

இதற்கிடையில், உலக சுகாதார மைய பரிந்துரைப்படி பாஸ்டியர் நிறுவனத்தில் மேற்கொள்ளப்பட்டு வரும் உற்பத்திமுறை, கட்டமைப்புப் பணிகளை ஆய்வு செய்ய, பார்லி நிலைக்குழுவினர் நேற்று பாஸ்டியர் ஆய்வகம் வந்தனர்.

ராஜ்ய சபா எம்.பி., விஜயலட்சுமி ராடோ, லோக்சபா எம்.பி.,க்கள் அசோக் ஆர்கால், லிங்கம், ஜெய்ஸ்ரீபன் கனுப ஹாய் படேல், ராகவன், ஆரூண், ராதே மோகன் சிங் மற்றும் அதிகாரிகள் உட்பட ஒன்பது பேர் அடங்கிய குழுவினர் ஆய்வுப் பணியை மேற்கொண்டனர்.

நிறுவன இயக்குனர் டாக்டர் சேகர், நிறுவனத்தில் மேற்கொள்ளப்பட்டு வரும் பணிகள், தேவைகள் குறித்து விளக்கினார்.

அதிகாரிகளுடன் கலந்தாய்வு நடத்திய கமிட்டியினர், நிறுவனத்தில் உள்ள நூலகத்தை பார்வையிட்டு, அங்குள்ள புத்தகங்கள் குறித்த விவரங்களை சேகரித்தனர். பின், தர பரிசோதனைக் கூடத்தை ஆய்வு செய்து, உற்கத்தி முறைகள் குறித்து அறிந்து கொண்டனர்.

குழுவினர் கூறகையில், மத்திய அரசின் ஆலோசனை யின் படி இந்த ஆய்வு நடக்கிறது. ஆய்வறிக்கை மத்திய அரசிடம் சமர்ப்பிக்கப்படும். மத்திய அரசு தான் ஆய்வறிக்கை குறித்த தகவலை வெளியிடும் என்றனர்.

தகவல்: தினமலர், 4 நவம்பர் 2011.

PARLIAMENT QUESTION – ANSWERS

RAJYA SABHA

Question No. 465
Answered on 06.09.2011

RESTRICTIONS ON SALE OF ANTIBIOTICS

465 Shri. S. Thangavelu

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

(a) whether Government has restricted the sale of 90 commonly prescribed antibiotics to put an end to the misuse of antibiotics;

(b) whether Government has also restricted sale of 16 medicines to tertiary care hospitals directly and sale of 74 medicines only on the prescription of registered medical practitioners;

(c) if so, the details thereof;

(d) whether All India Organisation of Chemists and Druggists, the apex body of over 7 lakh licensed medicines sellers, is against the move as due to an estimated loss of business worth Rs.5000 Crore for the retail medical stores across the country; and

(e) if so, the details thereof?

ANSWER

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

(a) to (e): A statement is laid on the Table of the Houe.
(a) & (b) No, Sir.

(c) Does not arise.
(d) & (e) Some representations have been received from various chemists and druggists associations, including the All India Organization of Chemists and Druggists, against the suggestions of the Task Force on Antimicrobial Drug Resistance inter alia for a separate Schedule under the Drugs and Cosmetics Rules to regulate the sale of antibiotics with a view to addressing the problem of multi drugs resistance arising out of widespread and indiscriminate use of antimicrobial drugs in the country.

Question No. 477
Answered on 06.09.2011

NON AVAILABILITY OF ESSENTIAL MEDICINES IN GOVERNMENT HOSPITALS

477 Shri. Sathish Chandra Misra

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

(a) the details of medicines covered under the National List of Essential Medicines;

(b) whether all these medicines are available at the hospitals run by Government; and

(c) if not, the reasons for the non-availability of these essential medicines in Government run hospitals?

ANSWER

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

(a) to (c): A statement is laid on the Table of the House.

(a) The objective of the National List of Essential Medicines (NLEM) is that the drugs included in it

are adequate to meet the common contemporary health needs of the general population of the country. It is the general obligation of the health administrators to ensure abundant availability of these drugs in the country. The NLEM is revised and updated from time to time in the context of contemporary knowledge of use of therapeutic products. The NLEM, 2011 contains 348 medicines belonging to 27 therapeutic categories such as antineoplastic, anti-cancer, immunological, anti-infective, Cardiovascular, ophthalmological preparations, Diuretics, anti-allergic etc. Medicines have also been categorized based on essentiality at different levels of healthcare viz.

(i) 181 Medicines for Primary (P), Secondary(S) and Tertiary (T) healthcare.

(ii) 106 Medicines for Secondary(S) and Tertiary (T) healthcare

(iii) 61 medicines for Tertiary (T) healthcare.

(b) & (c): The Central Government Hospitals viz. All India Institute of Medical Sciences, Dr. RML Hospital, Safdarjang Hospital and Lady Hardinge Medical College & Smt S.K. Hospital have their own hospital formularies / lists of essential medicines. All these essential medicines are made available to the patients on regular basis and as per requirement of users.

Question No. 208
Answered on 16.08.2011

SALE OF SPURIOUS AND SUB STANDARD DRUGS

208 Prof. P. J. Kurian

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to satiate :-
(a) Whether it is a fact that a number of spurious and sub-standard drugs are being sold in the country;
(b) if so, the details thereof;
© the number of cases registered in this regard, and conviction made, if any; and
(d) the details of steps Government would take for more stringent action in such cases?

ANSWER

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

(a) to (d): A statement is laid on the Table of the House.

(a) to (c) Some cases of manufacture and sale of spurious and sub-standard drugs are detected in different parts of the country by the State Drugs Control Authorities. However, there are no reports of any large scale manufacture of spurious and sub-standard drugs in the country. Recently, cases of spurious drugs have been unearthed by the State Drug Control Authorities of Haryana in Faridabad, the Drug Controller of Himachal Pradesh in Paonta Sahib and the officers of North Zone Office of CDSCO at Pilkhuwa, District Ghaziabad, U.P. Alert Notice regarding the drugs found in the seizures has been sent to all the State Drug Controllers by office of Drug Controller General (India) [DCG(I)]. The details of numbers of cases of spurious and sub-standard drugs detected and cases of convictions during the last three years are annexed.

(d) Following measures have been undertaken by the Government to help the drug regulatory authorities for taking stringent and speedy action in such cases:

(I) The Drugs and Cosmetics Act, 1940, has been amended in 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have been made cognizable and non-bailable.

(ii) A Whistle Blower Scheme has been announced to encourage vigilant public participation in the detection of movement of spurious drugs in the

country. Under this policy, the informers are suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics Act have been forwarded to the State Drugs Controllers for implementation.

(iv) Steps have been taken to strengthen the infrastructure including manpower of CDSCO to augment the enforcement capabilities at the national level. The States have also been requested to strengthen their infrastructure, including manpower at the State level.

(v) The inspectorate staff has been instructed to keep vigil and draw samples of drugs for testing / analysis to monitor the quality of drugs moving in the country.

(vi) The States / UTs have been requested to set up special Courts for speedy trial of offences under the Drugs and Cosmetics Act.

LOK SABHA

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE

Unstarred Question No. 2283
Answered on 12.08.2011

SPURIOUS AND SUBSTANDARD DRUGS

Shri SANJAY SHAMRAO DHOTRE, RAGHUVANSH PRASAD SINGH, K.C. SINGH BABA, PRIYA SUNIL DUTT, KADIR RANA, SURENDRA SINGH NAGAR, PREMDAS, GHANSYAM ANURAGI, KAMAL KISHOR, HAMDULLA A.B. SAYEED, SUBASH BAPURAO WANKHEDE, HAR SIMRAT KAUR BADAL, JAT POONAMBEN VELJIBHAI, JAGDISH THAKOR, BAID YANATH PRASAD MAHTO, KAUSHALENDRA KUMAR, DEEPA DASHMUNSI, P. VISWANATHAN, S. RAMASUBBU

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

(a) whether the Government has taken note of the various reports in the foreign media which declare India as the largest producer of spurious and substandard drugs and vaccines;

(b) if so, the facts in this regard;

(c) the steps so far taken by the Government to tackle the rising menace of spurious drugs and vaccines indicating the number of raids conducted along with the number of such cases detected during each of the last three years and the current year so far, State/UT-wise;

(d) whether the Government has recently constituted a Committee to tackle the problem of spurious drugs and vaccines in the country; and

(e) if so, the details of the recommendations made by the said Committee alongwith the follow up action taken/proposed by the Government thereon?

ANSWER

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

(a) & (b): The reports in the foreign media are not based on actual survey. The organisation for economic corporation and development in its

report published in 2010 had mentioned about the import of fake drugs from India in the European Union. The statistics mentions in the report were related to case of violation of Intellectual Properties Rights recorded in 2005 with TAXUD (European Community's Taxation and Custom Union). Such cases are considered as counterfeit medicines by European Union. The India Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 made thereunder do not, however, recognize linking of the licensing of any drug with its patent status. Nevertheless, the Government has taken up the matter with World Health Organisation as well as other international forums that patent issues should not be confused with the quality of medicines or spurious drugs. (c): The Government has taken following steps to check the problem of spurious drugs in the country:

(I) The Drugs and Cosmetics Act, 1940 has been amended in 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have been made cognizable and non-bailable.
(ii) Whistle Blower Scheme has been announced to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers are suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.
(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics Act have been forwarded to the State Drugs Controllers for implementation.
(iv) The inspectorate staff have been instructed to keep vigil and draw samples of drugs for testing/analysis to monitor the quality of drugs moving in the country.
(v) Steps have been taken to strengthen infrastructure, including the manpower of CDSCO for better enforcement. Similarly, State Governments have been requested to augment manpower and infrastructure.

A Statement containing three years data of the number of cases of spurious drugs, prosecutions launched and number of raids is annexed. Data for the current year has not yet been compiled.

(d) No.

(e): Does not arise.

ANNEXURE

Statement showing No. of Samples tested, No. of Samples declared not of Standard Quality, No. of Samples declared Spurious, No. of Prosecutions Launched, and No. Of persons arrested and Number Raids conducted during the last three years as per the feedback available from the States.

Sl. No.	Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious / adulterated	No. of prosecutions launched for manufacturing, sale and distribution of spurious/adulterated drugs	No. of persons arrested	No. of Raids conducted
1.	2008-09	45145	2597	157	220	133	2836
2.	2009-10	39248	1942	117	138	147	2513
3.	2010-11	49682	2372	95	167	72	1145*

* except the state of Uttar Pradesh.

GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE

Unstarred Question No. 3179
Answered on 19.08.2011

ADVERSE SIDE EFFECTS OF DRUGS

3179 Shri NITYANANDA PRADHAN
BAIJAYANT PANDA
RANJAN PRASAD YADAV

Will the Minister of Family and Health Welfare be pleased to state:

a) whether the Government has set up any mechanism and launched any project with All India Institute of Medical Sciences (AIIMS) as co-coordinating agency to monitor and combat the side/adverse effects of various drugs in the country;

(b) if so, the details thereof;

(c) the details of the drugs detected having adverse side effects in the country during each of the last three years and the current year; and

(d) the steps taken/proposed to ban the drugs having adverse side effects on human health?

ANSWER

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

(a) & (b): The Pharmacovigilance Programme of India (PvPI) was started by the Government on 14.7.2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC) for monitoring adverse drug reactions (ADRs) in the country. The NCC has now been shifted from AIIMS to Indian Pharmacopoeia Commission (IPC), Ghaziabad on 15.04.2011.

(c) : The NCC under AIIMS had reported about 8000 ADRs upto April, 2011. The NCC under IPC has collected 2442 ADRs so far.

(d): The decision to ban or withdraw a drug by the regulatory authorities is normally based on the risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safer substitutes and overall safety profile of the drug. These conditions are different for different countries. It is for this reason that a drug banned / restricted in one country may continue to be marketed in other countries. There is a well laid mechanism in India to review the status of the drug formulations as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been banned / withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the expert committees set up for the purpose, based on available technical information, benefit-risk ratio, local needs and availability of safer alternatives etc. Based on the recommendations of the expert committee, the Central Government prohibits manufacture and sale of drugs in the country through a Gazette Notification.

None of the ADRs reported under the pharmacovigilance programme have led to any restriction / prohibition of any drug in the country. However, because of safety issues and / or restrictions / bans imposed in other countries several drug formulations have been prohibited in the country.

GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE

Unstarred Question No. 2294
Answered on 12.08.2011

BANNED DRUGS

2294 Shri PREMCHANDRA GUDDU
BAIJAYANT PANDA

Will the Minister of Family and Health Welfare be pleased to state:

(a) whether the Government proposes to ban certain anti-depression/anxiety drugs including Deanxit which is banned in certain countries for its harmful side effects;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the details of the durgs banned by the Government during the last three years and the current year so far;

(d) whether the Government has taken note of the instances of prescription of these banned drugs by physicians in the country; and

(e) if so, the details thereof alongwith the action taken thereon?

ANSWER

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

(a) & (b): There is no proposal at present with the Government to ban anti- depression/anxiety drugs including Deanxit (FDC of Flupenthixol + Melitracen) in the Country. The drug 'Deanxit' is stated to be marketed in several European countries like Austria, Belgium, Italy, Bulgaria, Netherlands, Switzerland etc. The safety issue related to FDC of Flupenthixol + Melitracen was examined by an expert committee set up by the Drug Technical Advisory Board (DTAB) alongwith the subject experts and based on their recommendation the manufacturer has been asked to conduct clinical trial to establish the safety of the drugs.

(c) : A Statement containing the list of drugs banned by the Government of India during the last three years and the current year is annexed. However, the Gazette Notification GSR 82(E) dt.10.02.11 prohibiting the manufacture and marketing of the formulations of drugs viz. Nimesulide for pediatric use, Phenylpropanolamine, Cisapride, Human Placental Extract Sibutramine and R-Sibutramine has been challenged by the manufacturers in the Hon'ble High Court of Madras and the Hon'ble Court has granted interim stay of the said notification. Further, the said notification is respect of the drug "Human Placement Extract" manufactured by the firm M/s. Albert David Ltd. was challenged by the manufacturer in the Hon'ble High Court of Delhi in Writ Petion (Civil) no. 1054/2011. In pursuance of the order of the Hon'ble Court dated 6.4.2011, the Government amended the said notification in respect of the said drug by notification GSR 418 (E) dated 30.05.2011.

(d) & (e): The Government is not aware of instances of prescription of banned drugs by Physicians in the country. These drugs would otherwise not be available with the Chemist as their manufacture and sale is an offence under the Drugs and Cosmetics Act.

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