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TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2016

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

First of all we wish all our readers a very Happy New Year 2017.

We are happy to publish the 32nd issue of Pharma Web Newsletter for Oct – Dec 2016. We are happy to announce that our Chairman, Mr. S. V. Veerramani, presided over the 68th IPC, at Visakhapatnam, on 16 – 18th December 2016. There were about ten thousand delegate's attended the congress. As a president of this congress our chairman's inaugural address is published in this newsletter for the benefit of readers. We are also happy to inform that the Pharma Knowledge and Training Institute (Finishing School) under the aegis of our Trust conducting another series of Industrial Orientation Training programme for the final year Pharmacy students from 23rd January 2017 onwards

In this newsletter the following articles are also published

- Ø Role of Pharmacist in the Prevention & Management of Diabetes by Dr. Muthukumar Subramaniyan, CEO and Chairman – DiaSem Healthcare
- Ø Regulatory Requirements for Approval of Similar Biologics in India by Dr. V. G. Somani, Joint Drugs Controller (India) CDSCO, HQ, New Delhi

We have also published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules and also important circulars issued by DCGI.

We are happy to announce that our Trust sponsored the National Pharmacy Week Celebration, celebrated by IPA, TN Branch, during 25th November 2016. The celebration was well attended by students of Pharmacy form various colleges as well as Pharma professionals. It was conducted in The Tamilnadu Dr. MGR Medical University, Auditorium. The present Director of Drugs Control, Tamilnadu, Mr. S. Abdul Khader, was awarded as the Pharmacist of the year during the function. Dr. Muthukumar Subramaniyan, CEO and Chairman – DiaSem Healthcare, delivered the lecture on the theme of “Role of Pharmacist in the Prevention & Management of Diabetes”. Our Trust also instituted various awards like Scholarship for M. Pharm & Pharm D students, Essay competition and meritorious students from The Tamilnadu Dr. MGR Medical University.

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

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

With Best Regards,
R. NARAYANASWAMY
Chief Editor

QUALITY PHARMACEUTICALS AND PATIENT WELFARE

By
Mr. S. V. Veerramani,
Chairman, Tamilnadu Pharmaceutical Sciences Welfare Trust, President – IDMA, Mumbai
Chairman and Managing Director, M/s. Fourrts (India) Laboratories Pvt. Ltd.,
(Presidential address delivered during the inauguration of 68th IPC, at Visakhapatnam)

The theme for this 68th Indian Pharmaceutical Congress 2016 is "Quality Pharmaceuticals & Patient Welfare". I believe that without benefits and safety to our patients, whatever pharmaceuticals we produce, will be of no value. In order to make product safer and beneficial to the patients, quality attributes have to be built into the product, right from product development and through process excellence and quality systems, keeping patient welfare in the centre of all activities.

ELEMENTS OF QUALITY

Looking at the historical background of the term "Quality", it has evolved through different definitions over a period of time. Dr. J. Juran defined Quality as "fitness for use". Dr. E. Deming defined Quality as "uniformity and dependability" ISO defines Quality as "degree to which a set of inherent characteristics fulfills requirements".

Quality in pharmaceutical is supposed to manifest in four forma – Safety, Efficacy, Purity and Identity.

Safety:
Safety is the prime element of quality in pharmaceuticals. A pharmaceutical product is expected to be safe in an ailing patient, which means it should be free from undue reactions when used as directed.

Efficacy:
Efficacy is the ultimate purpose of a pharmaceutical product. A pharmaceutical product is expected to elicit the intended pharmacological activity/therapeutic response when used as directed.

Purity:
Purity is the standards set for a pharmaceutical product, as prescribed by the Pharmacopoeia. A pharmaceutical product is expected to comply with the predetermined specification throughout its shelf-life.

Identity:
Identity is the requirements for labeling the pharmaceutical product, as per the applicable regulations. Even a product which is safe, effective and pure will be termed as 'misbranded' if it is not labeled in a prescribed manner.While the first two element of quality – Safety and Efficacy are meant for patient welfare, the other two - Purity and Identity are controls on quality.

EVOLUTION OF QUALITY

The means to achieve this 'Quality' also have evolved through different phases. It started with a product-oriented approach known as the Quality Control (QC). Then process oriented approach, known as the Quality Assurance (QA), then finally into system oriented approach known as the Quality Management System (QMS). In this entire journey, the requirements of Good Manufacturing Practice (GMP) has also evolved as regulation to govern the pharmaceutical industry.

This 21st century has seen a big transformation in the quality system approach in the pharmaceutical industry. If we look at the elements of GMP in the past, it was more of 'Do's for compliance. Though the relevance of quality was cited everywhere, there was no ultimate reference to patient benefit. We could hardly find the words 'patient' or 'customer' in regulatory guidelines. Now there is a shift in focus from procedural compliance, quality to patient centric quality a paradigm shift from discrete GMP compliance procedures at each stage of the product lifecycle to a comprehensive quality systems approach over the lifecycle of the product.

Another major progress is the initiatives in the harmonization of technical requirements for drugs and drug products. International Conference on Harmonization (ICH) has accomplished a tremendous task in this regard and continues to achieve greater harmonization in the interpretation and application of technical guidelines in major subjects.

PATIENTS' EXPECTATIONS

Ultimately Quality is “meeting customer requirements”, here the prime customer for the pharmaceutical product is patients. Patients have four basic expectations of drug products;

a. to be effective, when used as directed
b. To be safe as labeled
c. To be available when needed
d. To be affordable

(A). TO BE EFFECTIVE, WHEN USED AS DIRECTED

Both pharmaceutical industry and regulators have roles to play to meet this expectation from the patients. Through the application of Pharmaceutical Quality System, the probability can be maximized to ensure the product effectiveness. Regulatory surveillance is the key control mechanism to deliver this to the patients.

"Pharmaceutical Quality System" (PQS) is now the order of the day. This is a holistic system, encompassing the lifecycle of the product- product quality originates from Product development, grows through Technology transfer to Commercial production till discontinuation of the product : This includes;

Pharmaceutical Development:

- Design a product and its manufacturing process to consistently deliver the intended performance and meet the needs of patients, health-care professionals, and regulatory authorities.

- To encourage designs for more efficacious, safe and economical drug delivery technologies, smoother regulatory compliance and improved patient acceptability.

- Develop knowledge of the product and processes to support the establishment of specifications and manufacturing controls.

- Utilize Quality Risk Management principles to identify and control risk to product quality

- Be aware of the importance of excipients, effects of its quality on the safety of the final formulation, changing regulatory requirements to ensure tighter controls and latest quality concepts related to excipients.

Technology Transfer:

- Transfer product and process knowledge between development and manufacturing environment

- Refine Quality Risk Management and control strategies

Commercial Production:

- Provide product with appropriate quality attributes consistently in a state of control and facilitating continual improvement.
- Continually expand product and process knowledge
- Adjust the Quality Risk Management and control strategy as needed

In other words, it is Quality by design in product development, followed by Quality in implementation in technology transfer and Quality through monitoring during commercial production. This quality system is intended to encourage the use of science and risk-based approaches at each lifecycle sage, thereby promoting continual improvement across the entire product lifecycle. This quality system demonstrates the commitment of industry and regulators to enhance the quality and availability of medicine around the world in the interest of public health. This system facilitates innovation and continual improvement in the industry towards patient benefit.

(B) TO BE SAFE AS LABELED

Safety is given utmost importance at every stage of the product lifecycle. This starts from the product development phase, wherein the clinical safety is required to be demonstrated for product approval. Subsequently, it is controlled during the commercial production through the application of GMP. Then the product safety is monitored through pharmacovigilance.

GMP demands the pharmaceutical industry to demonstrate its commitment and compliance towards patient safety. For example, the subject of cleaning validation – the GMP requirements and expectation on this subject has grown more and more in the past two decades to prevent the chances of cross contamination in pharmaceutical products towards patient safety. On the other side Pharmacopoeial standards are being regularly upgraded to strengthen the analytical methods and improve standards for product purity and performance. Few examples in the recent past for the control on impurities include the control on residual solvents, elemental impurities, extractables and leachable and ever expanding requirements for Related Substances in the individual monographs.

Pharmacovigilance

Pharmacovigilance activities are being implemented to add safety in the use of drug products. The objective of Pharmacovigilance is to enhance patient care and patient safety in relation to the use of medicines, by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines. The product safety is thoroughly scrutinized by regulatory authorities, before approving the new products. At this point, most medicines will only have been tested for short-term safety and efficacy in a limited number of carefully selected individuals. Once put onto the marker, a medicine leaves the secure and protected scientific environment of clinical trials and is legally set free for consumption by the general population. When the product is approved, and used in the larger group of the general population, some patients may exhibit particular and un predictable sensitivities. Hence it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under the real-life conditions, post release. More information is generally needed for use in specific population groups, like children, pregnant women and the elderly, and about the efficacy and safety of chronic use, especially in combination with other medicines. Experience has shown that many adverse effects, interactions (i.e. with foods or other medicines) and risk factors come to light only during post-marketing surveillance. Having a well –organized pharmacovigilance system helps to expand the product knowledge, thereby to reduce harm to patients and thus improve public health.

Nowadays there is increasing concern on counterfeiting of drug products, as threat to patient safety. Government and regulatory authorities are establishing various anti-counterfeiting mechanisms to prevent the entry of counterfeit products in the supply chain.

(C) TO BE AVAILABLE, WHEN NEEDED

The patient focus will be incomplete, without addressing the availability of drug products to patients, when needed. Nowadays, regulations provide due importance for an availability of medicine in addition to product quality. Risk-benefit evaluation is done by the regulators for product approvals. Yet more emphasis is needed on the availability of medicine, in the case of orphan drugs and for rare diseases.

(D) TO BE AFFORDABLE:

Last, but not the least, is the availability of Quality Pharmaceuticals at an affordable price. In the recent years, Indian Pharmaceutical Sector has emerged as one of the world's leading and fastest growing markets. The industry has acquired a

commendable position in the global pharma market as a supplier of high-quality, low-cost generic drugs. Here the key is “Quality Pharmaceuticals at the affordable price”. This statement sounds like an oxymoron in the pharmaceutical industry. This can be achieved through operational excellence and continual improvements. The cost of quality needs to be understood. Engineering industries have proven that investing in prevention and appraisal cost can reduce the cost of failure, hence the overall cost of the product. Hence this should be possible in pharmaceutical industries also.

REDUCING DISEASE BURDEN:

The Indian Pharmaceutical Industry has contributed significantly to improving the health indicators, such as life expectancy, infant mortality, birth rate and much more by making affordable medicines. The key factor for this achievement has been the availability of many affordable alternatives and choices to the doctors and hospital administrators in making informed decisions in prescribing the correct medicines.

- The annual average pace of decline in MMR (for the period 1990 to 2013) was much faster in India (4.5%) as compared to the global rate (2.6%)
- Additionally, mortality due to various diseases has reduced too.
- For instance, the Global Burden of Disease (2015) reports a decrease in mortality (between the years 2005 and 2015) as below on account of:

    - Lower respiratory infections (by 22.6%)
    - Diarrhoeal diseases (by 31.7%)
    - Tuberculosis (by 30.7%)
    - Neonatal preterm birth (by39.5%)
    - Neonatal encephalopathy (by 31%)

The Pharmaceutical industry needs to continue their contribution to reducing disease burden not only in Infectious diseases but also Lifestyle diseases like Diabetes and Cardiovascular disorders and make the medicines more available and affordable for the welfare of the patients.

PHARMACISTS' ROLE IN QUALITY PHARMACEUTICALS & PATIENT WELFARE

Pharmacists play a major role in ensuring that the quality pharmaceuticals actually lead to creating patient welfare. There is no question that quality pharmaceuticals are an absolute necessity for patient welfare. However, it is well-documented that quality pharmaceuticals can even produce harm if not properly taken by a patient. There are several important aspects that play a major role in transforming

quality pharmaceuticals into patient welfare. By far the most essential and proven aspect is the intervention by the pharmacist, which is necessary to ensure that quality pharmaceuticals generate the expected outcome in the patients without any safety issues such as adverse drug reactions (ADRs) or drug-drug or drug-food interactions. The 68th IPC theme and the scientific program emphasize the role of the pharmacist as not only involved in the discovery, development, production and management of the supply of quality pharmaceuticals, but also as the most qualified and well-trained professional, involved in dispensing the right medicine of the right quality, in the right dose, at the right time, with the right advice about the right way of taking medicines to get the right outcome and relief to the patient. Simply put pharmacist is the obligate requirement for the transformation of quality pharmaceuticals into patient welfare. The Pharmacy Council of India has out forward the Pharmacy Practice regulations 2015, which must be fully implemented all over the country to ensure that quality pharmaceuticals through pharmacist intervention generate patient welfare.

QUALITY CULTURE & RESPONSIBILITY OF INDUSTRY

Having detailed on Quality pharmaceuticals and patient welfare, let us look at the origin of this Quality Culture. The modern quality system clearly indicates that Quality Culture starts form the top in an organization and percolates down to the entire organization. The role of the top management is emphasized in providing the quality product. Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the quality system. Senior management is required to monitor the performance of the quality system for both internal and outsourced activities. Quality cannot be owned only by the “Quality Unit' entire management is accountable.

The sole purpose of the general manager of any company must be to build that trust and faith in doctors and patients, creating that quality culture and ecosystem all across the organization by making every employee understand the 'why' of our business, that we are in business because out there, there are diseases, out there, there are patients in need of quality medicines. If we create that internal understanding among all members of the organization working in all departments, that life is precious for all others as it is for me or my family members, we will move towards achieving “Made in India' medicine as the best medicine this entire world can get!

Why sometimes quality is a challenge for us is because of the clash between our belief and behavior. And we need to take care of this belief part to make everyone realize that it is an absolute must for us to keep the patient at the centre of everything we do. Most often we, the leaders do not communicate purpose and vision resulting in quality getting comprised sometimes due to conflict of interest between production, commercial and quality. If commercial puts pressure on production and production on quality, and if we miss just one step in the process, then we will be comprising patients' safety and this should not be the case.

The market exists because of patients and because of patients we discover drugs, manufacture drugs, market and sell drugs. And if there is any safety related issue or hazard we all are concerned.

Our patients are getting extremely well informed which is the right thing to happen. Today, they demand quality and we know that quality goes beyond manufacturing. Quality has become so important in day today life.

PATIENT SAFETY- A RESPONSIBILITY OF ALL STAKEHOLDERS

Patient safety is not only the responsible of manufacturers but also the responsibility of Distributors, Retailers, the entire supply chain and of course, the Regulators.

The manufacturers, besides their responsibility of product developments, Clinical Trials, and patient-centric manufacturing, should also need to act as a Facilitator in providing patient support and patient education. The distributors and retailers not only need to follow good distribution practices and good storage practices but also provide education to patients through their Pharmacist. They have a vial responsibility to prevent spurious medicines from coming into Supply Chain. The Regulators should not only be Enforces, but also Enablers for good and robust GMP adherence.

Pharmaceutical industry stands by the patients and for the patients. This is the profession where there should not be a conflict between profits and patient welfare. Ultimately this profession has 'Respect it holds for patient welfare" and "Responsibility it holds for actions towards patient benefit" and "Integrity it holds for doing what is right".

ARTICLES

ROLE OF PHARMACIST IN THE PREVENTION & MANAGEMENT OF DIABETES

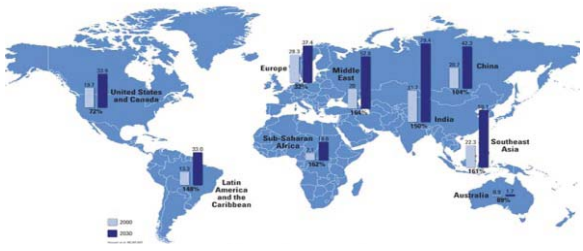
By
Dr. Muthukumar Subramaniyan,
CEO and Chairman – DiaSem Healthcare
(Lecture delivered on, 25th November 2016, National Pharmacy Week Celebration)

*The World Health Organization (WHO) defines **health** as the "state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity."*

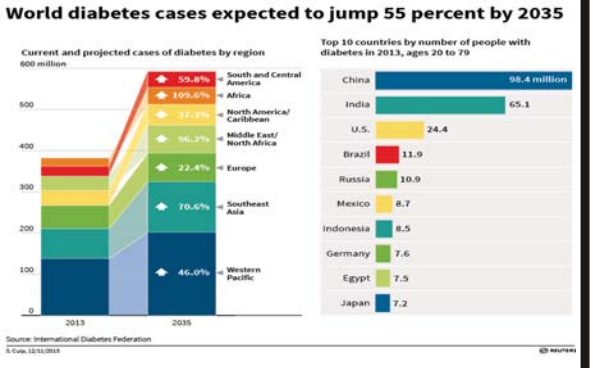
***Public health** is defined as **organized community efforts** to protect, promote, improve, or restore the community's or population's health.*

***Disease prevention** is defined as **activities** that are aimed to prevent and control disease, stop the disease processes or reduce the consequences of disease.*

GLOBAL PREVALENCE OF DIABETES



Global Prevalence of Diabetes
Source Hossain et al. NEJM 2007 (million people)



The need for paramedics' involvement in Diabetes prevention & management is the need of the hour

There is a need to have more pharmacists involved....

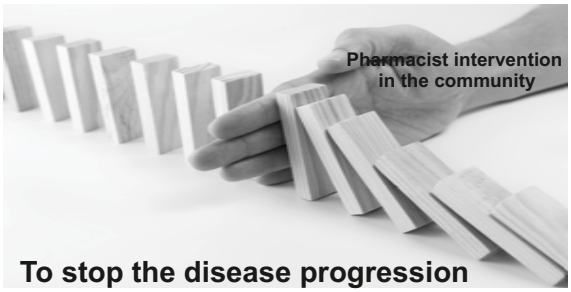
Your pharmacist is a competent, professionally qualified expert, who can help you derive maximum benefits

- ✓ Direct providers of care
- ✓ Members of interdisciplinary team
- ✓ Providers of pharmaceutical care
- ✓ Providers of products
- ✓ Consultants

National Pharmacy Association (NPA)

Mike Holden, Chief Executive of the National Pharmacy Association (NPA) says: "*Pharmacists play a key role* in the delivery of quality diabetes care. They are the most appropriately qualified to support patients on how to use their medicines to manage their condition. And they can *advise on recommended lifestyle and dietary interventions."*

ROLE OF PHARMACIST IN THE PREVENTION OF DISEASES



To stop the disease progression

Increased pharmacist involvement in health promotion and disease prevention measures would help decrease the financial and human costs, medication misuse, and drug abuse. (Crawford, 2005)

Neighbourhood Chemists Turn From Dispensing Drugs to Giving Advice

Dr. D. B. A. Narayana, a regulatory expert and Managing Trustee of DPT (Delhi Pharmaceutical Trust) has stated that patients rely on the "chemist", second to only the doctor itself; a fact borne out by a recent all-India study undertaken by the (DPT) (2011)

Do you know???

Your **PHARMACIST** is the vital link between you and your doctor in taking care of your health.

- ✓ What is the name of the medication (Brand or Trade Name) and what are the active ingredients (Generic name/s)?
- ✓ What is the medication supposed to do? Will it cure or relieve my symptoms?
- ✓ How long should I take it? Can I stop taking it earlier if I start feeling better?
- ✓ What are the most common side effects ? Are there any rare serious side effects ? What should I do if I experience side effects ?
- ✓ What if I forget to take my medications once or several times?
- ✓ Is it safe to become pregnant or breastfeed while taking this medication?
- ✓ How should I store my medications?
- ✓ Drug - Drug Interactions
- ✓ Drug – Food Interactions

REQUIREMENTS FOR THE COUNSELING PHARMACIST

Knowledge of the clinical and demographic characteristics of the community Targeted activities

Development of a written plan for informational and preventive efforts

Identification of collaborative community partners, such as health departments, community and advocacy groups

Marketing, documenting, and billing of professional services associated with health promotion and disease prevention in order to provide sustainable pharmacy-based interventions

Compliance aids: The compliance aids like medication envelopes and medication calendars can help in making the patient understand the different dosing schedule of the medication, (OHAs & insulins).

Utilization of educational materials, eg, handouts, brochures, Patient information leaflets (focussing on the lifestyle modifications and the medications), audiovisual aids counseling

Such a pharmacist is a vital member in the Diabetes prevention and management program

MEASURABLE

- ✓ Improvement in clinical markers
- ✓ Improvement in patients quality of life
- ✓ Improvement in patients knowledge of the disease
- ✓ Patient satisfaction with the services
- ✓ Decrease in overall health care cost, hospitalisations and complications of diabetes

IT ONLY TAKES ONE PERSON TO CHANGE YOUR LIFE.

Ruth Casey YOU

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Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purpose.

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

REGULATORY REQUIREMENTS FOR APPROVAL OF SIMILAR BIOLOGICS IN INDIA

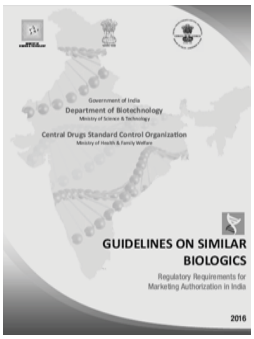
By

Dr. V. G. Somani

Joint Drugs Controller (India) CDSCO, HQ, New Delhi

(Lecture delivered on, 18th December 2016, 68th IPC, Visakhapatnam)

Agenda



- ❑ Introduction
- ❑ Background & Objectives
- ❑ Applicable Regulations and Guidelines
- ❑ Competent Authorities
- ❑ Scope
- ❑ Principles of Development of Similar Biologics
- ❑ Data requirements for Preclinical Studies
- ❑ Data requirements for Clinical Trial Application
- ❑ Post-Market Data for Similar Biologics

1. Introduction:

- A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability.
- This guideline address the pre-market regulatory requirements including comparability exercise for quality, preclinical and clinical studies and post market regulatory requirements for Similar Biologics.
- This guideline is not meant to substitute or rephrase the Rules made under Drugs and Cosmetics Act, 1940 or any other relevant Acts.

2. Background & Objectives

CDSCO

CDSCO is National regulatory authority in India that evaluates safety, efficacy and quality of drugs in the country.

DBT

DBT through Review Committee on Genetic Manipulation (RCGM) is responsible for overseeing the development and preclinical evaluation of rDNA derived products.

Previously, these Similar Biologics were approved by RCGM and CDSCO using an abbreviated version of the pathway applicable to new drugs on a case by case basis.

3. Applicable Regulations and Guidelines:

REGULATIONS

- Drugs and Cosmetics Act, 1940,
- Drugs and Cosmetics Rules, 1945 (and amendments)
- Rules for the manufacture, use, import, export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989 (Rules, 1989) notified under the Environment (Protection) Act, 1986.

GUIDELINES

- Recombinant DNA Safety Guidelines, 1990.
- Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other Biologicals, 1999.
- CDSCO guidance for industry, 2008
- Guidelines and Handbook for Institutional Biosafety Committees (IBSCs), 2011
- Guidelines on Similar Biologics: Regulatory Requirements for Marketing authorization in India 2012.

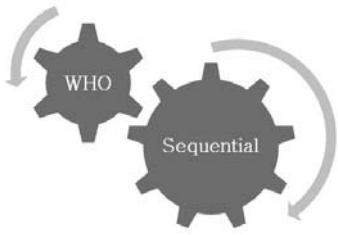
4. Competent Authorities

Institutional Bio Safety Committee (IBSC)	Review Committee on Genetic Manipulation (RCGM)
Genetic Engineering Appraisal Committee (GEAC)	Central Drugs Standard Control Organization (CDSCO)

5. Scope

These guidelines are applicable for Similar Biologics to be developed in India or imported into the country for marketing authorization.

6. Principles for Development of Similar Biologics



It is essential that the testing of the Similar Biologic be sufficient to ensure that the product meets acceptable levels of safety, efficacy and quality to ensure public health in accordance with international guidelines (WHO 2013)

6.1 Selection of Reference Biologic:

- Reference Biologic is an Innovator's product approved after evaluation of complete dossier

- Selection of the Reference Biologic:
  - Licensed / approved in India or ICH countries. Therefore another Similar Biologic cannot be considered as a choice for Reference Biologic.
  - The same Reference Biologic should be used throughout the studies supporting the safety, efficacy and quality of the product.
  - The active drug substance (active ingredient) of the reference biologic and that of Similar Biologic must be shown to be similar

- The acceptance of an innovator product as a Reference Biologic for evaluation of Similar Biologic does not imply approval for its use in India.

6.2 Manufacturing Process

- Manufacturing process to yield a comparable quality product in terms of identity, purity and potency to the Reference Biologic
- Validated and demonstrated to be highly consistent and robust.
- It is desired to use the same host cell line for manufacturing Similar Biologics. Alternatively any cell line that is adequately characterized and appropriate for intended use, with appropriate justification.
- Data requirements for review of manufacturing process at preclinical submission:
  - Complete description of manufacturing process.
  - Product characteristics:

•Molecular Biology Considerations

•Upstream Process Development

•Downstream Process Development

6.3: Quality Based Considerations for Similar Biologics

6.3.1 Analytical Methods:

- The analytical methods should be chosen for establishing product comparability as per the critical quality attributes of the product. (detect even "slight differences").
- To ensure the statistical analysis, each quantitative experiment should be done at least three times and data should be represented in terms of mean and standard deviation. Appropriate statistical significance should be represented throughout.

6.3: Quality Based Considerations for Similar Biologics

6.3.2 Product Characterization

Principles outlined in the ICH Q6B guideline should be followed.

- Structural and Physicochemical Properties
- Biological Activity
- Immunological Properties
- Purity and Impurities

6.3.4 Stability

- **Real-time** stability studies
- Representative of the **actual storage** containers and conditions, according to relevant guidelines (e.g. ICH Q1 A(R2), ICH Q5C, WHO TRS 822)
- Side-by side **accelerated and stressed stability** studies comparing the Similar Biologic to the Reference Biologic will be of value

6.3: Quality Based Considerations for Similar Biologics

6.3.4 Quality Comparability Study

- The applicant should submit a full quality dossier as per 2008 CDSCO guidance .
- Head-to-head characterization studies at active drug product level.
  1. Critical Quality Attributes (CQA) – must be controlled within limits
     a. Have direct impact on the clinical safety or efficacy.
     b. Directly impact the known mechanism(s) of action
  2. Key Quality Attributes (KQA) - KQAs must necessarily be controlled within acceptable limits; however it may acceptable to have slight differences.

7. Data required for Preclinical Studies

7.1 Prerequisite before Conducting Preclinical Studies

The applicant has to comply with the RCGM requirements

- Basic information about the Reference Biologic
- Basic information about the Similar Biologics

7.2 Preclinical Studies

- Comparative in nature and designed to detect differences, if any
- Conducted with final formulation intended for clinical use unless otherwise justified.
- Dosage form, dose, strength and route - same unless otherwise justified.

7. Data required for Preclinical Studies

7.2.1: Pharmacodynamic Studies

- **In vitro studies:** cell based bioassay
- **In vivo studies:** In vivo evaluation may be dispensable if in vitro assays are available, which are known to reliably reflect the clinically relevant pharmacodynamic activity of the Reference Biologic.

7.2.2: Toxicology Studies

- In case of in vivo toxicity studies, at least one repeat dose toxicity study in a pharmacologically relevant species with an intended route of administration.
- Duration- generally not less than 28 days with 14 days recovery period.
- Dose- based on the therapeutic dose of the Reference Biologic

7. Data required for Preclinical Studies

7.3 Immune Responses in Animals

- Antibody response to the Similar Biologic should be compared to that generated by the reference Biologic in suitable animal model

- The immunogenicity testing should be included as part of the sub-chronic repeated-dose study while developing the protocols

8. Data Requirements for Clinical Trial Application

Quality data submitted should indicate that there are **no differences** in CQAs, and that all KQAs are well controlled in order to allow the initiation of clinical evaluation.

8.1 Pharmacokinetic (PK) Studies

- The PK data should support the **subsequent** Phase III clinical development

- Performed in an appropriate number of: Normal Healthy Volunteers and / or Patients

- In **sequential development** approach, **NHV** study is performed before the Phase III.

8.1.1 Single Dose Comparative PK Studies

- Dosage should be within therapeutic dose range of reference Biologic.

- Route of administration - the sensitivity to detect differences is the largest.

- Sample size should have statistical rationale (i.e. statistically justified) and comparability limits should be defined and justified prior to conducting the study.

- The analytical method should be validated to have satisfactory specificity, sensitivity and a range of qualification with adequate accuracy and precision.
- A parallel arm design study is more appropriate for Similar Biologics with long half-life or for proteins for which formation of antibodies is likely or if study is being done in patients.
- In case of short half-life, cross over design may be considered with a scientific justification.

8.1.2 Multiple Dose Comparative PK Studies

- Multiple-dose, comparative, parallel arm steady state PK studies are required for a Similar Biologic:
  - that is used in a multiple dose regimen,
  - where markedly higher or lower concentrations are expected at steady state
  - where time-dependence and dose-dependence of PK parameters cannot be ruled out.
- In case multi-dose comparative PK studies are not done adequate justification should be provided.

8.2 Pharmacodynamic Studies

- Comparative, parallel arm or cross-over, PD study in most relevant population (patients or healthy volunteers) is required for detecting differences.
- Comparative PD studies are recommended when the PD properties of the Reference Biologic are well characterized with at least one PD marker validated for a clinical outcome of the molecule.
- The acceptance ranges for the demonstration of Similarity in PD parameters should be predefined and appropriately justified.
- The parameters investigated in PD studies should be clinically relevant and surrogate markers should be clinically validated.
- PD studies may be combined with PK studies, in which case the PK/PD relationship should be characterized.

8.3 Confirmatory Safety and Efficacy Study

- The study should be conducted in a sensitive and homogenous patient population with appropriate sensitive primary end points as per requirement of a Phase III clinical trial. One or more powered studies may be carried out
- Primary efficacy endpoints should be scientifically justified on clinical grounds.
- Equivalence, non-inferiority or comparability Phase III clinical trials
- The comparability Phase III clinical trials shall be conducted generally in not less than hundred evaluable patients in test arm to evaluate the safety, efficacy and comparability.
- Further, Phase IV clinical trials may be required to be conducted, generally in more than two hundred patients in continuation of comparability clinical trials.

8.3.1 Waiver of safety and efficacy study

- The confirmatory clinical safety and efficacy study can be waived if all are met:
  - Structural and functional comparability can be characterized
  - Comparable to in all preclinical evaluations conducted.
  - PK / PD study - comparability of PD markers validated for clinical outcome
  - A comprehensive post-marketing risk management plan has been presented
- The confirmatory clinical safety and efficacy study cannot be waived especially for large molecular weight biologics like Monoclonal antibodies.
- The confirmatory clinical safety and efficacy study cannot be waived if there is no reliable PD marker validated for clinical outcome.

For a product which is found Similar in pre-clinical, in-vitro characterization having established PK methods and a PD marker that is surrogate of efficacy, the residual risk is significantly reduced in the Phase I study if equivalence is demonstrated for both PK and PD. In such cases clinical trials may be waived.

8.4 Safety and Immunogenicity Data

- Both pre-approval and post-approval assessment of safety is desired
- Regarding pre-approval safety assessment, comparative pre-approval safety data including the immunogenicity data is required for all Similar Biologics including those for which confirmatory clinical trials have been waived.

  Comparative safety data based on adequate patient exposure (both numbers and time) must, in conjunction with the published data.
- From a safety and Immunogenicity perspective, if the firm conducts pre-approval studies that included more than 100 patients on the proposed Similar Biologic drug, the number of patients in phase IV study can be modified accordingly so that the safety data (from both Phase III and IV) is derived from a minimum of 300 patients treated with the Similar Biologics.

8.5 Extrapolation of Efficacy and Safety Data to Other Indications:

- Extrapolation may be possible if following conditions are met:
  - Similarity with respect to quality has been proven to Reference Biologic.
  - Similarity with respect to preclinical assessment has been proven to Reference Biologic.
  - Clinical safety and efficacy is proven in one indication.
  - Mechanism of action is same for other clinical indications.
  - Involved receptor(s) are same for other clinical indications.
  - However, new indications not mentioned by innovator will needs to be covered by a separate application.

10. Post-Market Data for Similar Biologics

It is important to establish a formal Risk Management Plan to monitor and detect both known inherent safety concerns and potential unknown safety signals.

10.1 Pharmacovigilance Plan

- Comprehensive pharmacovigilance plan should be prepared to further evaluate the clinical safety in all the approved indications in the post marketing phase
- The PSURs shall be submitted every six months for the first two years after approval of the Similar Biologic is granted to the applicant. For subsequent two years the PSURs need to be submitted annually to DCGI office as per the Schedule Y.

10.2 Adverse Drug Reaction (ADR) Reporting

All cases involving serious unexpected adverse reactions must be reported to the licensing authority as per Schedule Y.

10.3 Post Marketing Studies (PhaseIV Study)

- Additional safety data may need to be collected after market approval through a pre-defined single arm study of generally, more than 200 evaluable patients and compared to historical data of the Reference Biologic.
- The study should be completed preferably within 2 years of the marketing permission / manufacturing license unless otherwise justified.

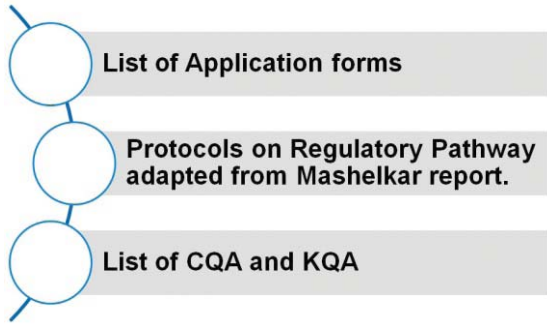
- Following should be considered for post marketing phase IV study protocol:
  - Primary endpoint: Safety
  - Secondary endpoint: Efficacy and Immunogenicity
- Regarding post-marketing safety and immunogenicity study at least one non-comparative post-marketing clinical study with focus on safety and immunogenicity (on case by case basis) should be performed.
- It is not mandatory to carry out additional non-comparative immunogenicity studies in post marketing studies, if immunogenicity is evaluated in clinical studies.

- When neutralizing antibodies are detected in patients in clinical studies, the impact of the antibodies on the PK/PD parameters should be analyzed.

Exceptions:

- In the case of Similar Biologics that can be evaluated for rare diseases, the clinical trial population size can be reduced as per the rarity and severity of the disease as well as the limitation of access to therapeutic options.

Other features:



TARIFF FOR ADVERTISEMENTS

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

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

Advertisement size

Page size : 24 cm x 18.5 cm

Print area : 20 cm x 16 cm

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

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

INFORMATION

M. PHARM & PHARM D SCHOLARHSIP 2016 – 2017

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awarded scholarship to selected M. Pharm & Pharm D final year students from various colleges in Tamilnadu & Puduchery for their on-going project work. The scholarship scheme was imitated in the year 1998. The received applications are codified, so that the identity of the student is not disclosed to the evaluator and sent to institutions outside the state of Tamilnadu for evaluation.

This was the 19th year of these awards, we have received 144 applications from seven different branches – six from M Pharm and Pharm D, from 18 institutions. All synopses were sent to Prof. B. Narasimhan, Dean – Faculty of Pharmaceutical Sciences, Maharishi Dayanand University, Harayana & his team for evaluation. Based on their ranking, 22 students have been selected for award for scholarship as per the following details:

College wise Applications – Break up

Sl. No	Name of the College	M. Pharm						Pharm D	
		PH	PC	PA	PG	PY	PP	CP	TOTAL
1	Madras Medical College		7		5	9			21
2	Madurai Medical College	5	3			6			14
3	The Erode College of Pharmacy	1							1
4	JSS College of Pharmacy	12		5	3		1	6	27
5	SRIPMS, Coimbatore	2		3			7	10	22
6	PSG College of Pharmacy	2			2				4
7	KMCH College of Pharmacy				1				1
8	Sri Ramachandra University	1					3	6	10
9	SRM University	2		6	1			7	16
10	Vels University							3	3
11	Adiparasakthi College of Pharmacy	4							4
12	Vinayaka Missions College of Pharmacy			1	1				2
13	Mother Theresa PG Research Institute				1	3			4
14	Nandha College of Pharmacy				1			4	5
15	Arulmigu Kalasalalingam College	2							2
16	Swamy Vivekananda College						2		2
17	Annamalai University							5	5
18	RVS College of Pharmacy							1	1
	TOTAL	31	10	15	15	18	13	42	144

PH – Pharmaceutics

PC – Pharmaceutical Chemistry

PA – Pharmaceutical Analysis

PG - Pharmacology

PY – Pharmacognosy

PP – Pharmacy Practice

CP- Clinical Pharmacy (Pharma D)

RESULTS

PHARMACEUTICS

Rank	Name	Institution	Amount (Rs.)
First	Ms. Tamal Kusum Das	J. S. S. College of Pharmacy, Ooty	12,000/-
Second	Mr. M. Raja	College of Pharmacy, SRIPMS, Coimbatore	10,000/-
Third	Mr. Subharaj Saha	J. S. S. College of Pharmacy, Ooty	8,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institution	Amount (Rs.)
First	Mr. V. Shiva Kumar	Madras Medical College, Chennai	12,000/-
Second	Ms. A. Menaka	Madras Medical College, Chennai	10,000/-
Third	Mr. M. Madhuraj	Madras Medical College, Chennai	8,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institution	Amount (Rs.)
First	Mr. Samrat Debnath	J. S. S. College of Pharmacy, Ooty	12,000/-
Second	Mr. S.T. Narenderan	J. S. S. College of Pharmacy, Ooty	10,000/-
Third	Mr. Birendra Kumar	Vinayaka Missions College of Pharmacy, Salem	8,000/-

PHARMACOLGOY

Rank	Name	Institution	Amount (Rs.)
First	Mr. A. Balasachidanandam	PSG College of Pharmacy, Coimbatore	12,000/-
Second	Ms. P. Percial	Madras Medical College, Chennai	10,000/-
Third	Mr. A. Vijaya Ragavan	PSG College of Pharmacy, Coimbatore	8,000/-
Consolation	Mr. D. Balaji	Mother Theresa Post Graduate and Research Institute, Puducherry	7,000/-

RESULTS

PHARMACOGNOSY

Rank	Name	Institution	Amount (Rs.)
First	Ms. M. Geethanjali	Madurai Medical College, Madurai	12,000/-
Second	Ms. S. Albee	Madurai Medical College, Madurai	10,000/-
Third	Ms. S. Shanmuga Priya	Madras Medical College, Chennai	8,000/-

PHARMACY PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Mr. Titto P Jacob	College of Pharmacy, SRIPMS, Coimbatore	12,000/-
Second	Ms.Jesni K Jose	College of Pharmacy, SRIPMS, Coimbatore	10,000/-
Third	Ms. Hesly Rajan	Swamy Vivekanandha College of Pharmacy, Tiruchengode	8,000/-

PHARM D – CLINICAL PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Ms. Debi Ann Abraham, Ms. M. Divya Krupa, Mr. A.R. Galileo, Ms. S. Janani	Sri Ramachandra University, Chennai	15,000/-
Second	Ms. Christy Mary Varghese, Ms. Divia Mathews, Ms. Dona Kurian, Mr. A. Fremil Jose	College of Pharmacy, SRIPMS, Coimbatore	12,000/-
Third	Ms. Anu Joy Thomas, Ms. Anu Maria Jose, Ms. Liz Mathew, Ms. Manju Rosy Jose	J S S. College of Pharmacy, Ooty	10,000/-

ESSAY COMPETITION 2016 - FOR FINAL YEAR B.PHARM STUDENTS

Tamilnadu Pharmaceutical Sciences Welfare Trust, also conducting Essay competition for the final year B. Pharm Students and this was the 6th year of these awards. An essay competition of the subject: "Educate Next Generation Pharmacists & Patients" was conducted for the final year B. Pharm students studying in various Pharmacy colleges in Tamilnadu and Puducherry.

We received totally 84 applications from 10 Colleges and it was evaluated by Dr. P. K. Lakshmi, Professor & Head, G. Pulla Reddy College of Pharmacy, Hyderabad. Based on their best marks, 3 students have been selected for awards as per the following details:

College wise Applications – Break up

S.No	Name of the College	No of Applications	Awardees
1.	RVS College of Pharmaceutical Sciences, CBE	5	
2.	Vels University, Chennai	22	
3.	College of Pharmacy, SRIPMS, CBE	5	
4.	Sri Ramachandra University, Chennai	2	
5.	JKK Nataraja College of Pharmacy, Namakkal	4	
6.	Periyar College of Pharmaceutical Sciences, Trichy	2	
7.	Jaya College of Pharmacy, Thiruninravur	12	
8.	Vinayaka Missions College of Pharmacy, Salem	4	1
9.	K K College of pharmacy, Chennai	4	
10.	Swami Vivekananda College of Pharmacy, Thiruchengode	13	1
11.	Arulmigu Kalasalingam College of Pharmacy, Krishankoil	9	1
12.	Mother Theresa PG Research Insitutue, Puducheery	2	
	TOTAL	84	

RESULTS

Rank	Name	Institution	Amount (Rs.)
First	Ms. P. Vidyalakshmi	Vinayaka Mission's College of Pharmacy, Salem	10,000/-
Second	Ms. R. Ramya	Swamy Vivekanandha College of Pharmacy, Namakkal	8,000/-
Third	Ms. V. Veeralakshmi	Arulmigu Kalasalingam College of Pharmacy, Krishnankoil	7,000/-

The above awards sponsored by M/s. Pharm Products Pvt. Ltd., Thanjavur, in the memory **Shri. G. Swaminathan,**

University Merit Award - B. Pharm passed out students 2016

The toppers of B. Pharmacy in The Tamilnadu Dr. MGR Medical University, Guindy, Chennai are awarded. These awards are imitated in last year (2015), this is the 2nd year of these awards and the awardees are as follows

S. No.	Name	College	Prize Amount (Rs.)
1	561282020 – Krithika. E	PSG College of Pharmacy, Coimbatore	8,000/-
2	561282042 – Ram Pravin Kumar. M	PSG College of Pharmacy, Coimbatore	6,000/-
3	561286059 – Vigneshwar. M	Jaya College of Pharmaceutical Sciences, Chennai	6,000/-
4	561290033 – Nivedha. M	Aaadhi Bhagavan College of Pharmacy, Cheyyar TK	6,000/-

The above awards sponsored by **M/s. Fourrts (India) Labs. Pvt. Ltd., Chennai**

EVENTS

55th NATIONAL PHARMACY WEEK CELEBRATION, IPA – TN BRANCH

55th National Pharmacy Week Celebration was celebrated by Indian Pharmaceutical Association, Tamilnadu Branch on 25th November 2016 at 5.00 PM in The Tamilnadu Dr MGR Medical University, Guindy, Chennai. Dr. S. Geethalakshmi, Vice Chancellor, The Tamilnadu Dr. MGR Medical Univeristy, preside over the function. The guests of honors were Mr. S. Abdul Kahder, Director of Drugs Control, Tamilnadu, Dr. S. Manivannan, Deputy Drugs Controller, CDSCO, South zone, Chennai, and Mr. Srini Srinivasan, Managing Director, Pfizer, Chennai. Mr. M. M. Yousuf, President, IPA, TN Branch welcomed the gathering. Dr. Muthukumar Subramaniyan, CEO & Chairman, DiaSem Healthcare Pvt Ltd., addressed the gathering on the theme **"Pharmacists for Healthy India: Role in Prevention and Management of Diabetes".** Mr. Srini Srinivasan, Managing Director, Pfizer, gave a lecture on Emerging Carrier opportunities in Pharma Industries

Mr. S. Abdul Khader, Director of Drugs Control, Tamilnadu, was awarded as Pharmacist of the year sponsored by M/s. Lalchand Bhimraj, Chennai.

Tamilnadu Pharmaceutical Sciences Welfare Trust, instituted various awards to the pharmacy graduates as well as students and the same were distributed during this function. The awards such as "M. Pharm / Pharm D Scholarship", "B. Pharm Essay Competition" sponsored by M/s. Pharm Product Pvt Ltd., Tanjavur and University Merit award to B. Pharm students sponsored by M/s. Fourrts (India) Pvt Ltd., Chennai. The function concluded by vote of thanks by Mr. J. Jayaseelan, Secretary, IPA, TN Branch

The function was sponsored by Tamilnadu Pharmaceutical Sciences Welfare Trust and TANIPA Trust.

55th NATIONAL PHARMACY WEEK CELEBRATION, IPA – TN BRANCH

Two days Certification Course programme on "Export Import Management" Conducted by Pharmexcil at Chennai

Pharmexcil had conducted a Two days Certification Course programme on "Export Import Management" at Hotel Savera, 146, Dr. Radhakrishnan Salai, Mylapore, Chennai - 600 004, during 14th & 15th December 2016.

This Course organized by Pharmexcil is a Skill development programme for the member exporters. The programme is aimed at imparting training which is essential for the Officials in the Export Department. The programme will help the MSME Sector in the Pharma Industry in skill development. The main objectives of this course is to educate the various intricacies of International Trade - Documentation, Procedure, FEMA guidelines and different payment mechanisms and also educate about various stages of exports & imports in a systematic & methodical manner with special focus on the Pharma Sector. There were 36 participants who had attended this Certification course programme. Prof. Ajit Shah, from Universal Connections was a faculty who had conducted this Certification course programme.

Dr. A.R. Venkatesh, COA Member, Pharmexcil, welcomed all the participants and introduced them to Prof. Ajit Shah. He also briefed them about the role of Pharmexcil. Mr. T. Sathish, Honorary Secretary, IDMA - Tamil Nadu, Kerala & Pondicherry State Board, informed participants about growth made by domestic Pharmaceutical Industry. He informed that such programme is very helpful for new entrepreneur who want to start their new business in Pharma exports. Mr. J. Jayaseelan, Chairman, IDMA - Tamil Nadu, Kerala & Pondicherry State Board, thanked Pharmexcil for conducting such course in Chennai.

Two days Certification Course programme on "Export Import Management" Conducted by Pharmexcil at Chennai

From left to right Mr. Mohan babu, Pharmexcil Chennai office, Mr. Navin Kamble, Pharmexcil Mumbai office, Mr. S.V.P.S.Sivanandhan,Director, M/s Ceego Labs Pvt. Ltd., Dr A.R. Venkatesh, COA Member, Pharmexcil, Mr. J. Jayaseelan, Chairman, IDMA - Tamil Nadu, Kerala & Pondicherry State Board and Prof. Ajit Shah, Universal Connection

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 21st September, 2016

G.S.R. 897(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 705(E), dated the 19th July, 2016, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 19th July, 2016, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 19.07.2016;

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

Now, therefore, in exercise of the powers conferred under section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs

Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1)These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2016.

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

2. In the Drugs and Cosmetics Rules, 1945,

(a) in Schedule D(I), in item 2, for "sub-item 2.3", the following shall be substituted, namely:—

"2.3 A copy of Good Manufacturing Practice (GMP) certificate as per WHO – GMP guidelines or Certificate of Pharmaceutical Products (CPP) or written confirmation for active substances exported to European Union which is equivalent to GMP certificate issued as per WHO – GMP guidelines, by the National Regulatory Authority of the country of origin or a copy of the certificate equivalent to GMP certificate as per WHO GMP guidelines issued by National Regulator of United States of America or Japan or Australia or Canada or the European Union for the purpose of marketing of the drugs in their country, in relation to bulk drugs or formulations or special product meant for import into India."

(b) in Schedule D(II), in item 1, for "sub-item 1.4", the following shall be substituted, namely:-

"1.4 GMP certificate as per WHO-GMP format, or Certificate of Pharmaceutical Products (CPP), or written confirmation for active substances exported to the European Union which is equivalent to GMP certificate issued as per WHO – GMP guidelines, by the National Regulatory Authority of the country of origin or a duly notarised copy of the certificate equivalent to GMP certificate as per WHO-GMP guidelines issued by United States of America or Japan or Australia or Canada or the European Union for the purpose of marketing of the drug in their country."

[F. No. X.11014/01/2016-DFQC]
K. L. SHARMA, Jt. Secy.

Note.- The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1), dated 21st December, 1945 and last amended vide notification number G.S.R. 789(E), dated 12.08.2016.

File No. 12-01/14-DC (Pt. 47)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotala Road, New Delhi 110002

Date: 02-08-16

CIRCULAR

Subject: - Restriction of conducting three clinical trials per investigator-regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards restriction that no investigator shall conduct more than three trials at any given period of time, it has been decided to remove this restriction & it is further decided that Ethics Committee after examining the risk and complexity involved in the trial being conducted/proposed shall decide about how many trials an investigator can undertake.

This is communicated for information and necessary compliance by all concerned.

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

To:-

I) All stakeholders through website of DCG (I).
II) Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).

Copy to:-

I) PS to Secretary, Ministry of Health and Family Welfare,
II) PPS to DGHS,
III) PS to AS,
IV) PS to JS(R).

File No. 12-01/14-DC (Pt. 47)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotala Road, New Delhi 110002

Date: 02-08-16

CIRCULAR

Subject: - Requirement of 50 bedded site for clinical trial-regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards condition that no clinical trial shall be conducted at site having less than 50 bedded hospital, it has been decided to revise this condition & it is further decided that Ethics Committee shall examine & decide whether the clinical trial site is suitable for trial or not irrespective of number of bed.

However, it was also suggested that site shall have emergency rescue and care arrangements along with all other necessary facilities required for that particular clinical trial.

This is communicated for information and necessary compliance by all concerned.

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

To:-

I) All stakeholders through website of DCG (I).
II) Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).

Copy to:-

I) PS to Secretary, Ministry of Health and Family Welfare,
II) PPS to DGHS,
III) PS to AS,
IV) PS to JS(R).

File No. 12-01/14-DC (Pt-47)
Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110002

Dated 03.08.2016

Circular

Subject: Requirement of NOC from DCGI for addition of new clinical trial site or investigator-regarding.

To deliberate stake holders concerns and the way forward relating to some issues on conduct of clinical trial in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including secretary, D/o Health Research and Director General, ICMR and Director General of Health Services were present.

As regards requirement of NOC from DCGI for addition of new clinical trial site or Investigator in clinical trial, it was decided in the meeting that the respective Ethics Committee after due diligence can approve proposals for addition of site(s) and investigator(s) and no NOC from DCGI in the normal course, should be necessary. However, the applicant would inform DCGI about any such addition /deletion and thereafter, if no objection was received from DCGI, it would be deemed to have concurrence of CDSCO.

This is communicated for information and necessary compliance by all concerned.

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

To:-

I. All stakeholders through website of DCG(I).
II. Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ)

Copy to:-

I. PPS to secretary
II. PPS to DGHS
III. PPS to AS (Food and drugs)
IV. PS to JS (R)

File No 12-01/14-DC (Pt-47)
Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, New Delhi

Dated 03.08.2016

Circular

Subject- Requirement of approval of Review Committee on Genetic Manipulation (RCGM) under Department of Biotechnology for r-DNA derived drugs like Insulin, Monoclonal antibody etc.-regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trial in India, two meetings were held on 20.08.2015 and 06.10.2015 under the chairmanship of secretary, Ministry of Health and Family welfare in which experts including secretary, D/o Health research and Director General, ICMR and Director General of Health services were present.

As regards requirement of approval of Review Committee on Genetic Manipulation (RCGM) under Department of Biotechnology for r-DNA derived drugs like insulin, Monoclonal antibody etc., it was decided in the meeting that the applicant may submit parallel application to RCGM and DCG (I) seeking approval to conduct clinical trial. However, DCG (I) shall complete the scrutiny of application and issue permission, only after RCGM clearance was received.

This is communicated for information and necessary compliance by all concerned.

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

To:-

I. All stakeholders through website of DCG(I).
II. Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ)

Copy to:-

I. PPS to secretary
II. PPS to DGHS
III. PPS to AS (Food and drugs)
IV. PS to JS (R)

To be Published in the Gazette of India Extraordinary Part-II, Section - 3, Sub-Section (ii)

Government of India
Ministry of Commerce & Industry
Department of Commerce
Directorate General of Foreign Trade
Udyog Bhawan

Notification No. 19 /2015-2020
New Delhi, Dated: 4 August, 2016

Subject: Import/export policy for Human Biological Samples for commercial purposes: amendment Schedule – 1 (Import Policy) and Schedule – 2 (Export Policy) of ITC (HS), 2012.

S.O. (E): In exercise of powers conferred by Section 3 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby inserts Import Policy for Human Biological Samples for commercial purposes under General Notes 17 to Schedule – 1 (Import Policy) and Export Policy for Human Biological Samples for commercial purposes under General Notes 4 to Schedule – 2 (Export Policy) of ITC (HS), 2012 as under:

> "The import of human biological samples by the Indian diagnostic laboratories / Indian Clinical Research Centres for lab analysis / R & D testing or export of these materials to foreign laboratories should be permitted by Customs authorities at the port of entry / exit without prior approvals (import licence / export permit) from any other Government agency, provided the concerned Indian company / agency submits an undertaking that they are following and will follow all the applicable rules, regulations & procedures for safe transfer and disposal of the biological samples being imported / exported as per the related norms / regulations set by WHO* / DGFT** [SCOMET items in Export Policy of ITC (HS), 2012, Schedule – 2 (Export Policy)] / Ministry of Environment, Forests and Climate Change***, Government of India, to the Customs authorities at the port of entry / exit along with the details of such samples".

2. Effect of this Notification: Policy condition for import /export of human biological samples for commercial purposes is laid down.

* (i) http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1)
(ii) http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf

** http://dgft.gov.in/exim/2000/scomet/scomet2011.pdf

*** (i) http://envfor.nic.in/legis/env/env1.html
(ii)http://envfor.nic.in/legis/hsm/hsm3.html

(Anup Wadhawan)
Director General of Foreign Trade
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[Issued from F.No.01/89/180/Misc.82/AM-05/PC-2 (A)]

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File No. 18-1/2016-DC (S.No:04) (Shelf Life Extension)
DIRECTORATE GENERAL OF HEALTH SERVICES
OFFICE OF DRUGS CONTROLLER GENERAL (INDIA)
(IMPORT & REGISTRATION DIVISION)

FDA Bhawan, Kotla Road
ITO (Near Bal Bhawan), New Delhi

Date: 27 OCT 2016

Circular

This is to inform that office of Drugs Controller General (I) is receiving various application for extension of shelf life within or up to the period of 60 months for export purpose of drugs which are not specified in Schedule 'P' of Drugs and Cosmetics Rules which does not come under the purview of office of Drugs Controller General (I). Therefore applicants are required to approach concerned State Licensing Authorities for said purpose.

However, application for extension of shelf life beyond 60 months are required to be made to office of DCG (I) as per Drugs and Cosmetics Act and Rules.

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

File No. X-11026/143/16-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

DATED: 13/12/2016

Circular

Subject: NOC for export of biological products (Vaccine & r-DNA products) under Form 29 License to manufacture drugs for purposes of examination, test or analysis-regarding.

It is learnt that many applicants are requesting this office for issuance of export NOC for the batches manufactured under Form 29 License for commercial purpose.

In this regard, it is clarified that the product manufactured under Form 29 license can be exported only for the purpose of examination, test or analysis including clinical evaluation involving human subjects and not meant for commercial purposes as per Drugs and Cosmetics Rules.

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

To,

i. All Stakeholder through website of CDSCO
ii. Zonal / Sub-zonal offices of CDSCO
iii. All officers of CDSCO (HQ)

File No: X-11026/143/16-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

Dated: 13-12-2016

OFFICE MEMORANDUM

Subject: Form 29 License to manufacture drugs for purposes of examination, test or analysis for biological products (Vaccines & r-DNA products)-regarding.

In order to promote research & development of new drugs, it has been decided to discontinue the practice of prior joint inspection for issuance of Form 29 licenses to vaccine & r-DNA products.

The applicant shall submit application along with self declaration (in format enclosed) to State Licensing Authority & Central Licensing Authority by hard copy and also by e-mail (dci@nic.in, testlicensebio@cdsco.nic.in and on email of the concern State Licensing Authority). The State Licensing Authority shall issue Form 29 Licenses within three working days of receipt of application.

The receipt of Form 29 License shall also be confirmed by applicant on email to CDSCO, within three working days.

The joint inspection of such applicants shall be carried out after issuance of Form 29 Licenses, using the risk based approach.

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

To:

All State/UT Drugs Controllers
All Zone/Subzone Offices of CDSCO
All CDTL/CDL

LEGAL UNDERTAKING ON NON JUDICIAL PAPER

I.....S/o.....being authorized signatory in the company at address..... do hereby solemnly affirm and state as under that:-

1. I / We undertake to state that the product.....shall be manufactured by M/s..... at.....

2. I/ We undertake to state that condition of Form 29 under Drugs and Cosmetics Rules will be followed by the undersigned & batches meant for clinical trial/study will be manufactured in compliance with Good Manufacturing Practice (GMP).

(Name & Signature of Applicant)

Date:

Place:

Sick Pharmaceutical Units Under NCB Scanner after Drug Haul

The arrest of an Indian Air Force Wing Commander in Maharashtra, a scientist in Hyderabad, and his wife based in Bengaluru, by the Narcotics Control Bureau over the last week for allegedly funding the manufacturing of amphetamine has thrown light on how small pharmaceutical factories are illegally being used to make the drug.

NCB officials seized 231 kg of amphetamine, a stimulant, and over Rs. 1 crore in cash.

One of the accused, Venkatarama Rao, is a scientist working in a chemical company in Bengaluru and has a house in Hebbagudi, Bengaluru. “Lured by easy money, he started making amphetamine in the lab of a loss-making pharmaceutical manufacturing unit in Hyderabad. He used to travel frequently between the two cities,” said an NCB officer.

He would make the drug in Hyderabad and bring it to his house in Bengaluru in his car or tell his accomplice Ravishankar Rao to arrange the logistics. Venkatarama Rao and Ravishankar Rao were arrested in Hyderabad on September 30 when they were allegedly transporting the drug to Bengaluru. “Drug dealers used to come to his house in Hebbagudi or Hyderabad and take the consignment from there. He had customers from different parts of the country and other South Asian countries,” said an NCB officer.

During interrogation, the scientist revealed about a cash transaction that was about to take place in his Hebbagudi house on October 1. The officers went to Hebbagudi and intercepted a man who was carrying over Rs. 1 crore in a travel bag. “We believe that he is a subordinate of Wing Commander Rajasekhar Reddy. We have detained him for questioning,” the NCB officer said. The NCB also seized 31 g of the drug from the house and arrested Venkatarama Rao's wife, Preethi.

“We believe that Rajasekhar Reddy is funding the manufacturing of drugs. The NCB sleuths arrested him in the Nanded police station limits when he was trying to flee to Goa a few days ago,” an NCB officer said.

The NCB officers said that Venkatarama Rao and Rajasekhara Reddy are both from Andhra Pradesh and were classmates. “They met again when Rajasekhar Reddy was posted at the Software Development Institute of the Air Force in Bengaluru,” said the officer.

Further investigation is on to check whether they were selling any other form of drugs in the city.

Bengaluru NCB officers said that they are keeping track on sick pharmaceutical units in Hyderabad and Karnataka. These drug manufacturing units are financially ailing and can sometimes be used to manufacture drugs illegally. “Most often the owners lease it out to some third parties who, without the knowledge of the owner, use it to manufacture drugs. We are checking if the lab in Hyderabad had taken permission from the Drugs Control Department,” an officer said.

M. Devesh, Chairman, Narcotic Drugs and Psychotropic Substances Committee, Indian Drug Manufacturers Association, said that a manufacturing licence from the State Food and Drug Administration was needed to manufacture drugs and there was a provision for loan licence for other Companies under the Drugs & Cosmetics Act.

”For manufacture of any psychotropic substance, a company needs to register with the Central Bureau of Narcotics and file quarterly returns. If this is not being done, then it's an illegal operation,” he added.

Source: The Hindu, 6th October 2016

FDA Seizes 'Wonder' Drugs Worth Rs 1 Crore Across Maharashtra

Food and Drug Administration (FDA) officials seized products worth Rs 1.52 crore from various parts of the state during a special drive against misleading advertisements last month. Ninety-four raids were conducted during the month-long drive. As many as 263 products claiming to cure diabetes, obesity, impotency, short height, mental disorders, cancer and rheumatism were seized by the officials in Mumbai, Thane, Pune, Nagpur, Nashik, Kolhapur, Aurangabad and the Konkan region.

"The special drive was taken up after several complaints about objectionable advertisements. It was carried out simultaneously in all seven administrative divisions," state FDA commissioner Harshadeep Kamble told TOI. Products seized during the raids included a sugar-like syrup for diabetic patients and herbal solutions claiming to cure obesity, enhance virility and increase physical height.

"Some seized products include Abhay Medari Slim Fit Syrup, Stay-on, Fat Go Capsule, V-slim Capsule, 303 capsule, Sugar Nashak Vati, My Fair Cream, RV Caps, DyeMedica, Ashvatul DX Capsule, Long Height Extra Strong Capsule, Fat cure ras, Look Like-16 among others," Kamble said.

As per provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, no person can take part in the publication of any advertisement referring to any drug which suggests or leads to the use of that drug for diagnosis, treatment, mitigation or cure or any disease mentioned in the schedule to the Act.

There are 54 diseases/disorders conditions mentioned in the said schedule. Such advertisements are published in newspapers and magazines, and appear on TV and other media.

Source: *The Times of India, 8th October 2016*

Indian Drug Regulator May Scarp Licence Renewal Move may Affect Quality of Medicines

India's drug regulator proposes to scrap the renewal of licences and approvals for manufacturing and selling drugs and cosmetics in the country as part of efforts to remove hurdles and improve the ease of doing business, moves that some experts said would affect the quality of medicines.

Provisions of the Drugs & Cosmetics Rules of 1945 are being revisited to consider if the validity of licences and approvals can be made perpetual, the Central Drugs Standard Control Organisation (CDSCO) and in a notice dated October6. It also proposes a similar system for laboratories that test drugs.

The licences and approvals can be made perpetual provided they are not cancelled or suspended by the licencing authority, according to the notification.

For industry, this change would remove the need to periodically renew licences for the manufacture, sale and distribution of products. Right now, drug companies are required to renew the licences to sell their products every five years.

"However, there should be assessment of compliance with the conditions of licences/approvals at least once in 10 years," GN Singh, the Drugs Controller General of India, said in the notice to state drug regulators and pharma industry associations.

The CDSCO is also considering upgrading Good Manufacturing Practices to make them at par with the World Health Organization's guidelines, according to the notice. The regulator has sought comments, suggestions and inputs on the proposed moves by October 21.

Scrapping of licence renewals would be a step back in upholding patient interest, said Leena Menghaney, South Asia regional head of the Access Campaign at Médecins Sans Frontières. According to her, the proposed gap between compliance assessments is too long and renewing of licences needs to be implemented properly instead of being scrapped.

"It is already clear that manufacturers have been de-facto enjoying licences in perpetuity. The CDSCO, as seen in the court cases surrounding the revocation of marketing approval for irrational fixed dose combinations, finds it very difficult to revoke them even on grounds of public health," said Menghaney. "Licences should be renewed and it should not be merely a renewal on paper through payment of fees."

At the time of renewal, it is important to address all information pertaining to good manufacturing practices and the source of active pharmaceutical ingredients used to give the drug its therapeutic effect and any other variation that the manufacturer may have implemented, she added.

However, GMP consultant Ranjit Barshikar said there would be no detrimental effect on public health and the quality of medicines. "(The licences are) no doubt perpetual, but there will be assessment once in 10 years for licencing compliance. This doesn't mean that DCGI will not do GMP inspections," he said.

The Indian Pharmaceutical Alliance, Indian Drug Manufacturers' Association and the Organisation of Pharmaceutical Producers of India did not immediately respond to phone calls and emails from ET seeking comment.

The government is said to be planning a major overhaul of the country's drug policy, with moves that include scrapping the need to renew manufacturing licences and easing regulations to allow medical and drug research here. The numbers of drugs under price control has also been brought up as part of this discussion.

Source: *The Economic Times, 8th October 2016*

Be Warned, Common Blood Pressure Drugs May Increase Risk of Depression

Have you ever felt depressed when taking medicines for blood pressure? Turns out some commonly prescribed blood pressure pills may increase risk of mood disorders such as depression or bipolar disorder.

"Mental health is under-recognised in hypertension clinical practice, and the possible impact of antihypertensive drugs on mental health is an area that physicians should be aware of and consider if the treatment of high blood pressure is having a negative impact on their patient's mental health," said Sandosh Padmanabhan, Professor at University of Glasgow in Britain.

In this study, researchers compared four common classes of antihypertensive drugs and risk of mood disorders.

They collected data on 525,046 patients (ages 40-80) from two large secondary care Scottish hospitals.

The researchers selected 144,066 patients being treated for hypertension with either angiotensin antagonists, beta blocker, calcium channel blockers or thiazide diuretics.

They were compared to a group of 111,936 patients not taking any of those drugs.

Researchers followed the patients for five years documenting hospitalisation for mood disorders, such as depression or bipolar disorder.

After more than 90 days on the antihypertensive medications, the study published in the American Heart Association's journal Hypertension, found that there were 299 hospital admissions, predominantly due to major depression, among the patients studied, at an average 2.3 years after patients began antihypertensive treatment.

Patients on beta-blockers and calcium antagonists were at two-fold increased risk of hospital admission for mood disorder, compared to patients on angiotensin antagonists.

Patients on angiotensin antagonists had the lowest risk for hospitalisation with mood disorders compared to patients on other blood pressure meds and patients on no antihypertensive therapy.

Patients taking thiazide diuretics showed the same risk for mood disorders compared to patients taking no antihypertensive drugs, the study found.

Source: *The Hindustan Times, 11th October 2016*

Long- Acting Malaria Pill Now Gets A Step Closer

Scientists have developed a new drug capsule that remains in the stomach for up to two weeks after being swallowed, gradually releasing its payload, paving the way for a long acting pill that may effectively treat malaria and many other diseases

This type of drug delivery could replace inconvenient regimens that require repeated doses, which would help to overcome one of the major obstacles to treating and potentially eliminating diseases such as malaria.

Researchers at Massachusetts Institute of Technology (MIT) and Brigham and Women's Hospital in the US used this approach to deliver a drug called Ivermectin, which they believe could aid in malaria elimination efforts.

Source: *The Times of India, 18th November 2016*

Band Aid-Like Device to Monitor Heart

Researchers have developed a tiny, soft and wearable acoustic sensor that measures vibrations in the human body, allowing them to monitor heart health and recognize spoken words. The device captures physiological sound signals from the body and can be mounted on anybody surface, said Jae-Woong Jeong of University of Colorado Boulder, US.

Source: *The Times of India, 18th November 2016*

Environmental Lobby Groups Blame Production Methods of Drug Companies for Rise in Drug-Resistant Bacteria

India's commerce ministry has hit back at reports by environmental lobby groups which have blamed the production methods of Indian drug companies as one of the main reasons for the rise of super bugs, or drug resistant bacteria. The Pharmaceuticals Export Council of India (Pharmexcil) set up by the Ministry of Commerce and Industry under foreign trade policy on Thursday said that it is noticing a "disturbing trend in such reports".

"In the recent past, there was much of adverse propaganda against Indian companies with the intention of maligning the image of Indian pharma, and ultimately depriving the developing world of having access to quality drugs manufactured by Indian companies at an affordable cost," Pharmexcil said in its note.

The reaction by the pharma body comes a week after Changing Markets, an environment lobby group's investigation found that three Indian drug companies – Aurobindo Pharma BSE 0.82%, Orchid Chemicals and Pharmaceuticals BSE -1.34% and Asiatic Drugs and Pharmaceuticals - - were causing drug reisitant bacteria due to their polluting manufacturing practices.

The report found resistance to three major classes of antibiotics -- cephalosporins, carbapenams and fluroquinolones - - in four of the manufacturing sites. At eight of the sites under investigation, resistance to cephalosporins and floroquinolones was dedected.

Pharmexcil said that the report has selectively targeted at India and named some select exporters such as Aurobindo. It said statements like "70% of e-coli bacteria present in water originating from the perimeter of Indian company are resistant to fluoroquinolones" is not supported by facts or reference as the unit of Aurobindo Pharma that was inspected does not manufacture the ciprofloxacin formulation.

"The above observations make us believe that the report is not based on verified facts and is baseless and concocted to cause confusion in the minds of general public and international drug procurement agencies and in turn disturb the Indian pharma Industry business", the pharma body said.

Source: *The Economic Times, 27th October 2016*

Huge Haul of Banned Mandrax Tablets in Udaipur

In a huge haul, the Directorate of Revenue Intelligence (DRI) has confiscated 23.5 tonnes of banned Mandrax tablets at Udaipur, Rajasthan.

On a tip-off, a team of DRI officers raided the premises of Marudhar Drinks in Udaipur on October 28. During the searches, the officials detected a hidden room full of cartons of Mandrax tablets.

It contained about 2 crore tablets, which have been seized.

The tablets, estimated to be worth over Rs. 3,000 crore, were meant for illegal exports to Mozambique and South Africa, Central Board of Excise and Customs (CBEC) Chairman Najeeb Shah told a press conference. “The party drug, a depressant, overdose of which can lead to coma and death, is used as a recreational drug in Africa and Asia,” Mr. Shah said.

He said Bollywood producer Subhash Dudani, the alleged mastermind of the syndicate that manufactured acetic anhydride, a major ingredient of Mandrax, and imported or locally procured other raw materials, had been arrested. Mr. Dudani was nabbed in Mumbai and sent to Udaipur on transit remand.

The operations to nab others involved in the drug syndicate were under way, Mr. Shah said.

Owned by kingpin's nephew

The pharmaceutical factory in Udaipur and its two warehouses in Rajsamand, where the seizure was made, are owned by Ravi Dudani, nephew of the Dubai-based kingpin Subhash Dudani.

Subhash, the key person behind the narcotic drugs racket, lives in Dubai and had come to Mumbai to celebrate Diwali with his family.

The Border Security Force arrested Subhash at the Mumbai airport on Tuesday and brought him to Udaipur for questioning.

According to sources, Subhash has been detained along with Ravi in the BSF Camp at Kavita village situated 10 km away from Udaipur.

The Udaipur police were kept out of the loop of the joint operation by the DRI, the Central Bureau of Narcotics and the BSF.

The BSF has taken charge of security outside the factory and its warehouses, while the building has been covered with a tent.

Team members fall sick

Some members of the raiding team fell sick due to exposure to the white powder used for manufacturing the drug.

Rajasthan Home Minister Gulab Chand Kataria admitted that the police failed to get clues about the narcotic drugs racket.

Source: *The Hindu, 2nd November 2016*

Government May Disband National Pharmaceutical Pricing Authority

In a major overhaul of the country's drug policy, the government is likely to soon disband the National Pharmaceutical Pricing Authority (NPPA) in its present form and assume the power to set prices of essential medicines, as it seeks to address concerns that excessive controls were stifling innovation and competitiveness of the sector.

The revamped policy will also delink price control from essential medicines. Under the current regime, the moment a drug is brought under the list of essential medicines, it is subject to the price control mechanism.

The new system will be more flexible and prices will be regulated only when required. Senior government officials also decided last month to do away with the system of periodic renewal of licences for manufacturing and sale of drugs in the country. Licences will soon be granted for perpetuity.

These decisions follow a meeting last month at the PMO.

The meeting was attended by Niti Aayog CEO Amitabh Kant, Pharmaceutical Secretary Jai Priye Prakash, Health Secretary CK Mishra and DIPP Secretary Ramesh Abhishek

ET had reported on October 4 that Kant had written to health ministry to do away with stringent regulatory regime in the sector as this was creating unnecessary hurdles for drug companies and was totally against the concept of ease of doing business in India.

The NPPA was set up as independent drug price regulators in 1997 and currently over 450 medicines are under price control. A senior government official said henceforth, the right to regulate prices as and when required would rest with the government.

“Drug price control order may be delinked from the national list of essential medicines and, the NPPA, in its present form and current function may be wound up and deployed in the department of pharmaceuticals with a new mandate,” said the official.

The official said licences granted under the Drugs and Cosmetics Rules for manufacturing and sale would be issued for perpetuity, 'subject to their being withdrawn, suspended, cancelled or surrendered'.

It has been further decided that heath ministry will put in place a system for third-party certification and self-certification on annual basis. The usual process of regular inspections will continue.

These steps are being taken with a view to optimise the full potential of India's pharmaceutical sector.

It is estimated that the sector has the potential to grow to $55 billion in revenues by 2020 from $20 billion in 2015. The sector has attracted foreign investment worth $14 billion since 2000 and it's the sixth-largest recipient of FDI across all industry categories.

Source: *The Economic Times, 3rd November 2016*

Generics vs Big Pharma, Reloaded

The proposal to extend the time limit for State-level drug regulatory approvals from four to 10 years could hit the generics market

In a scathing letter to the Government of India, the Indian Pharmaceutical Alliance (IPA) took issue with what it considered to be a backdoor extension for data exclusivity norms in the country. It pointed to the recent government proposal to change the four-year time limit for State-level drug regulatory approvals to 10 years, arguing that this effectively results in a long and damaging data exclusivity.

Data exclusivity is a kind of intellectual property protection wherein clinical trial and other data submitted by an originator drug company cannot be used or relied upon by a drug regulatory authority to approve a generic version of that drug for a certain period of time. The notion is that without such protection, the originator company lacks the necessary commercial incentive to conduct expensive trials and take a potential drug to the market. Blocking generic entry for some years will, the theory goes, help drug companies invest in clinical trials.

Skewing the Pharma market?

India has long resisted U.S. and EU pressure to institute data exclusivity norms, seeing it as a barrier to generic entry and more affordable drug prices. However, a rather curious provision in the Drugs and Cosmetics Act (DCA) could arguably constitute a de facto kind of data exclusivity.

Under the Act as it stands now, a new drug continues to remain "new" even after it has been approved once by the Central regulator (Drugs Controller General of India, or DGCI) upon submission of local clinical trial data establishing safety and efficacy in India. However, it loses "newness" after four years, which means a drug manufacturer can short-circuit the process and go directly to a State regulatory authority and procure drug approval. It is this four-year period that is now sought to be enhanced to 10 years, an extension that the IPA argues constitutes an enhancement of data exclusivity norms in favour of large pharma companies, particularly MNCs. Others insist that there is no such data exclusivity norm in India.

Who is right? And who is wrong? This depends in large part on the kind of data that generic companies have to submit in order to gain approval for their follow-on drugs. If they are forced to submit the same kind of clinical trial data that originators have submitted to the regulatory authority, then this does amount to data exclusivity. For almost all generics will simply wait for the term (four years) to expire rather than undertake the expensive process of generating clinical trial data afresh, not to mention the sheer immorality of repeating animal studies and subjecting human volunteers to safety and efficacy tests in relation to the same drug molecule.

It is for this reason that world over, generic drugs are approved upon a simple showing of bio-equivalence: that the claimed molecule is the same as the one already approved. And therefore, there is no sense in having the generic applicant repeat all clinical trials afresh. However, bio-equivalence cannot be had for the asking but must be demonstrated through rigorous studies/data.

Unfortunately, our Act is not very clear on the kind of studies/data that a generic applicant is meant to submit, not least because it is one of the worst drafted pieces of legislation, leaving the bulk of substantive norms in the "rules" and various forms and schedules running to a good 500 pages!

Little wonder then that a number of state regulators do not insist on bio-equivalence studies or any other studies for that matter prior to approving a drug for manufacture in that State. Therefore, any substance held out as a drug (even a complex cancer drug) is likely to make the cut… be it a piece of chalk, cheese or china!

And this precisely is why in our rather complicated federal structure of drug regulation, comprising both a Central authority, namely the DCGI, and a vast array of State-level regulators, drug manufacturers opt to simply wait for four years and then approach State authorities rather than risking a more rigorous Central clearance.

However, this does not mean that all is well on the Central regulatory front. A damning parliamentary committee report some years ago found that in the vast majority of cases, the DCGI doesn't even insist on separate local clinical trial data for new drugs. Rather they routinely dispense with the requirement of local clinical trials under a broad "public interest" exception.

Lax regulatory standards

In the end, one needs to ask: why have this four-year or 10-year time lag at all for generic drug approval? Shouldn't generic drugs be approved on Day One, so long as they are able to demonstrate (through bio-equivalence studies and the like) that they are as robust as the new drug that has already been approved once? Why maintain this legal fiction that a drug will remain "new" even after it has been validly approved once (for up to four years or 10 years as the case may be)?

Unfortunately, our drug regulatory regime is callous at best, and murderous at worst, plagued with glaring gaps that are routinely exploited by drug majors — a fact amply demonstrated by a well-researched public interest petition (PIL) by whistle-blower Dinesh Thakur. Unfortunately, the apex court declined to admit his PIL and we lost out on an opportunity to compel a healthier drug regulatory regime.

Pollution is easy to understand. Drug regulatory standards not so. Which may perhaps explain why courts routinely entertain PILs on the former, but shy away from the latter. Even when lax regulation on the latter count is far more dangerous than pollution. For, with each passing day, we're suffering a regime that kills, albeit all too softly, through a laxity in the law. A laxity that the layman may not immediately grasp. But one which a responsible government (and even judges) should make it their business to study and understand, before it is too late.

Source: *The Hindu, 23rd November 2016*

Lower Drug Prices Helped Buyers Save 5K Crore in 3 Years

The government told the Lok Sabha on Tuesday that stringent measures to keep prices of essential medicines low have led to an estimated savings of around Rs 5,060 crore for consumers over the last three years.

In 2015, the government revised the price control order to bring under its purview more drugs. Currently, the government has fixed prices of around 850 essential medicines and is expected to cap prices of more drugs soon as part of its steps to make medicines affordable.

As per the provisions of the DPCO 2013, the drug regulator -National Pharmaceutical Pricing Authority - has fixed the prices of medicines appearing in the list of essential medicines, minister of state for chemicals and fertilisers Mansukh L Mandaviya said in a written reply in the Lok Sabha. "The action of the government has resulted in savings to the consumers to the tune of around Rs 5,060.30 crore, which includes medicines for critical diseases," he added. Earlier, the government had implemented the Drugs Price Control Order (DPCO) in May 2013 based on the National Pharmaceutical Pricing Policy of 2011 which had expanded the span of price control to cap MRPs of as many as 348 essential medicines. This was a departure from the previous regime which had only 74 bulk drugs or key raw material under price control and MRPs all formulations containing those bulk drugs were regulated by the government.

In a separate reply, the government said it has been taking steps, including Pradhan Mantri Jan Aushadhi Yojana, to make quality medicines available at affordable prices.

With a view to achieving the objective of making available quality medicines at affordable prices, the government has been taking several regulatory and fiscal measures from time to time, " Mandaviya said.

Source: *The Times of India, 23rd November 2016*

Prescription Drugs At Unlicensed Salons May Leave Indelible Scars

The Directorate of Drugs Control has seized prescription drugs worth `10 lakh from 11 salons in the city -amounting to nearly half of last year's haul, in only seven months this year.

For years, drug inspectors have scoured godowns and pharmacies to meet their monthly quota of seizures of spurious and substandard medicines. This year, probably for the first time, beauty parlours and salons came under their scanner. Officials seized skin ointments, creams for hair growth and botox injections from these centres, most of which were located in commercial hubs in the city.

The move came in the wake of the death of a medical student following a hair transplant procedure at a salon in Nungambakkam in May. Drug inspectors were directed to check out similar centres, especially those that offered skin lightening, hair growth and laser treatments. Director of drugs control Abdul Khader said although many of these centres had a doctor on their rolls, they were not allowed to stock or sell prescription drugs. "Cosmetics can be sold if they are from registered manufacturers, but prescription drugs can't be sold by them," he explained, adding that the quality of the seized drugs is now being investigated.

A source in the directorate said one of the skin ointments, after being tested, was found to have an ultrapotent steroid - clobetasol propionate -used to treat extreme skin conditions like acute eczema or psoriasis. “The component, in this case, was being `prescribed' to lighten the skin tone,“ he said.

From aromatherapy to nips and tucks, an increasing number of spas and parlours in the city are expanding their services, much to the chagrin of doctors. They suspect that many of these procedures, including treatments for anti-ageing, are either carried out without medical supervision or under the direction of doctors who aren't qualified.

“These days, anyone can become a cosmetologist,“ said Dr D Dinesh Kumar, vice-president of Indian Association of Dermatologists, Venerologists and Leprologists, Tamil Nadu chapter. He said the danger in cosmetic treatment need not necessarily be due to invasive procedures but because of an allergic reaction to a drug. “Only a dermatologist will tell you that your skin is lightening not because of the medicine but because it has steroids. Your skin is thinning,“ he said, adding that the ointment doesn't just work on the skin but enters the circulatory system causing long-term health ailments like diabetes.

Although, the state medical council says it is unethical for doctors to conduct invasive procedures at a nonmedical centre, there are no regulations barring them from seeing patients in the confines of a salon. “On the other hand, though the rule books prevent non-medical professionals from conducting therapies, there is no monitoring authority to keep a check on such centres”, said Dr J A Jayalal, president incharge of the council. He stressed on the need for a law. “We have no laws to regulate spas, salons or parlours. Along with the clinical establishment bill, we need to include specifics about doctors practicing in such establishments that are registered as shops”.

Source: *The Times of India, 25th November 2016*

Sanofi Pasteur Unveils 6-in–1 Paediatric Vaccine

Sanofi Pasteur announced the introduction of paediatric 6-in-1 vaccine, Hexaxim, which provides protection against six major childhood diseases in India. The ready-to-use fully liquid vaccine provides protection against diphtheria, tetanus, pertussis (whooping cough), polio, haemophilus influenza B and hepatitis B, Sanofi Pasteur said. It is indicated for primary and booster vaccination of infants and toddlers from six weeks to 24 months of age. Sanofi Pasteur India, Nepal and Sri Lanka Country Head Jean—Pierre Baylet said, “Hexaxim brings to life Sanofi Pasteur's mission to improve human health by developing innovative vaccination solutions against infectious diseases.”

Source: *The Hindu, 25th November 2016*

U.S. FDA Nod for Natco's Generic Budesonide Pills

Natco Pharma Ltd on Thursday said it had received final approval from the U.S. Food and Drug Administration for the Abbreviated New Drug Application it had filed for the generic version of Budesonide capsules. NATCO and its marketing partner Alvogen plan to introduce the product in the U.S. market immediately, Natco said in a regulatory filing. Perrigo Pharma International DAC sells Budesonide capsules, which is used in the treatment of certain bowel conditions, under Entocort brand in the U.S. market. Entocort capsules and its generic versions had U.S. sales of approximately $ 370 million during the 12 months ended December 2015, it said.

Source: *The Hindu, 25th November 2016*

Room-Temp Vaccines Can Reach Remote Areas

Scientists have developed three simple and inexpensive additives to stabilise vaccines at room temperature for a long time, an advance that will allow them to be shipped to remote areas in developing countries.

Researchers from Supramolecular Nanomaterials and Interfaces Laboratory (SUNMIL) in Switzerland were able to achieve this by using minute quantities of nanoparticles, polyethylene glycol, or higher amounts of sucrose.

The study addressed viral-vector vaccines, the most common type of vaccine, which normally only last a few days at room temperature. At that point, the viral components of the vaccines lose their structural integrity.

The researchers applied their methods to a vaccine that is currently in development. They were able to stabilise a vaccine against Chikungunya for 10 days, and then successfully inoculated mice with it.

Source: *The Times of India, 1st December 2016*

Sun Pharma Arm Picks up 14.6% Stake in U S Firm

Sun Pharma said its subsidiary has invested $13 million (about Rs.88 crore) in the U.S.-based scPharmaceuticals Inc. “One of the wholly-owned subsidiaries of the company has acquired 13,000,000 Series B preferred stock of scPharmaceuticals Inc (equivalent to 14.58 per cent fully diluted equity stake on conversion) by way of allotment,” Sun Pharmaceutical Industries said in a BSE filing. It further said: “Consideration for Series B preferred stock acquired is $13 million.” scPharmaceuticals Inc is a United States-based pharmaceutical company developing a portfolio of pharmaceutical products for subcutaneous delivery.

Source: *The Hindu, 24th December 2016*

Pharma Firms Warned That 'Regulator is Watching'

Warning that the "regulator is watching", Union Health Secretary C.K. Mishra said the State drug regulators were only following standard procedures by inquiring into the quality of drugs being supplied in the domestic market.

Drug regulators in seven States across India sent notices to 18 pharmaceutical companies, saying that nearly 27 medicines manufactured by these companies had failed quality tests.

A report in an English daily said that while the crackdown on substandard medicines has been under way since March, only one of the 18 companies had recalled a substandard drug from the market and two had stopped distribution of batches of inferior quality drugs.

Many deficiencies

"We have asked for reports from the State drug regulators. The message is simple, the regulators are watching. This is routine procedure and we have been doing it from time to time," Mr. Mishra said. The drug regulators of Karnataka, West Bengal, Andhra Pradesh, Maharashtra, Gujarat, Kerala and Goa have pointed out various deficiencies with regards to labeling of the drugs, dosage and so on.

Meanwhile, the report on nearly 48,000 drug samples surveyed as part of the National Drug Survey is expected to be tabled in the winter session of Parliament. The 400-page report covers the survey over two years by the National Institute of Biologicals (NIB) to gather evidence about the extent of spurious drugs in the Indian markets. This is the first pan-Indian survey, said G.N. Singh, Drug Controller General of India, who heads the Central Drug Standard Control Organization (CDSCO).

Sample test

According to the National Centre of Biotechnology Information (NCBI), in 2009, the Indian government sampled 24,136 drugs of 62 brands in a nationwide survey. "Samples were drawn from over 100 pharmacy outlets from various regions of India, which belonged to nine therapeutic categories of 30 manufacturers. Survey affirmed that only 11 products (0.046 per cent) were spurious," stated the paper by A.N. Khan and R.K. Khar.

In the last few years, CDSCO has been cracking down on companies that make falsified/spurious or substandard drugs. According to the Health Ministry, 35 cases of substandard quality were reported during 2009-2010, 35 in 2010-2011 and 34 cases in 2011-2012.

Source: *The Hindu, 29th November 2016*

Sun Pharma to Acquire Novartis' Cancer Drug

Sun Pharmaceutical Industries, India's biggest drug company, has announced plans to acquire a branded oncology product, Odomzo, from Novartis for an upfront payment of $175 million (Rs.1,188 crore).

An agreement has been signed between subsidiaries of both companies and the deal will close following anti-trust clearance and other closing conditions. Switzerland-based Novartis AG will get an additional milestone payment from Sun Pharma as per the deal while Sun Pharmaceutical will have to market the product globally. Odomzo was approved by the USFDA in July 2015.

Odomzo is used for the treatment of locally advanced basal cell carcinoma (laBCC) in adult patients that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. Approximately 70 per cent of the prescribers are dermatologists and the rest are oncologists for this class of drug.

According to IMS Health, the sales of the hedgehog pathway inhibitor grew by 40 per cent in October 2016, compared with the same month a year earlier.

Skin cancer

Non-melanoma skin cancer is the most common form of skin cancer globally. BCC accounts for approximately 80 per cent of non-melanoma skin cancers, accounting for more than 2 million estimated cases in the U.S. alone, according to a statement from Sun Pharma.

BCC consists of abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the outermost layer of the skin. It occurs most frequently on the head and neck, with the nose being the most common site, according to the statement. Jesper Jensen, Head, Biologics and Dermatology, Sun Pharma said, “This acquisition has the potential to leverage and expand the relationships that our Levulan sales team have with the dermatologists that treat common pre-cancerous skin conditions.”.

Source: *The Hindu, 29th November 2016*

Cipla's Inhaler Sereflo Gets U.K.Regulatory Nod

Pharmaceutical firm Cipla's inhaler 'Sereflo', used for treatment of asthma, has received final approval from the U.K. Medicines and Healthcare products regulatory agency (UKMHRA). The company's metered dose inhaler product, Sereflo (Fluticasone and Salmeterol) has been given final approval by the U.K. MHRA, Cipla said in a filing to BSE. Sereflo is a 25 mcg/125 mcg and 25 mcg/250 mcg are generic equivalent to Glaxo SmithKline's Seretide inhaler and is indicated for asthma treatment it added. “Seretide inhaler, for the aforementioned strengths, had U.K. sales of approximately $278 million for the 12 month period ending June 2016, according to IMS Health, “Cipla said.

Source: *The Hindu, 24th December 2016*

Demonetisation Erodes Over Rs 3.8 K Cr FMCG Sales

Demonetisation has hit the FMCG Industry hard. And, its hope for a recovery after a good monsoon seems unlikely at present.

While FMCG companies had been witnessing cautious consumer spending latest data from market researcher Nielsen shows sales of the industry have gone down by 1-1.5% or Rs 3840 crore in November; compared to October: “While 1-1.5% net impact of demonetization does not look huge, considering the size of the FMCG industry at Rs 2.56 lakh crore, this is a large drop in terms of absolute value, “said Nielsen.

And, the industry's problems can become bigger: Data revealed that retailers are stocking goods lesser than ever before due to cash and supply constraints. Their purchase in November has gone down by 6.4% compared to October.

Purchase of personal care items such as, toilet soaps, toothpaste and shampoo has seen the steepest decline by retailers. The fall in off take is driven by urban India (-3.1% Nov vs Oct), while rural India has managed to stay flat at 0.4% mainly due to smaller packs, smaller currency transactions and a flourishing barter system.

Chemists could ride out the impact because they grew in rural areas, according to Nielsen, and were allowed to accept old currency till November 24.

On the consumer front, one out of five housewives reduced spending by 50% or more. While they have cut spends across categories, Nielsen expects a more cutback for impulse categories (biscuits/salty snacks) compared to everyday essentials (atta/rice/pulses/sugar).

Source: *The Times of India, 24th December 2016*

Lupin gets FDA nod to sell BP medicine in U.S.

Drug major Lupin has received tentative approval from the US health regulator to sell Olmesartan medoximil tablets, used for treating high blood pressure, in the American market. “It has received tentative approval for Olmesartan medoximil tablets from the US Food and Drug Administration (USFDA), “ Lupin Ltd said in a BSE filing on Monday. Olmesartan medoximil tablets, generic version of Daiichi Sankyo's Benicar, are indicated for the treatment of hypertension, along with other anti-hypertensive agents to lower, BP it added.

Source: *The Hindu, 27th December 2016*

GM Vaccine for Malaria Without Side Effects Soon

A potent malaria vaccine with virtually no side-effects has cleared clinical trials. The new “highly protective” malaria vaccine was successful in humans and can pave the way for treatment of other parasitic diseases.

Scientists from the US genetically engineered the plasmodium parasite that causes the disease, after being passed on from mosquitoes, to remove three genes that lead to infection. Although they can't multiply, they live in the liver and stimulate the body's defences to repel a real infection.

Plasmodium parasites first infect the liver and then blood, leading to more than 200 million infections and nearly half a million deaths worldwide in 2015. “The most clinically advanced vaccine in development contains fragments of the malaria parasite and is only partially protective,“ said James Kublin from University of Washington.

Vaccination with whole, live-attenuated parasites offers an alternate approach, but its potential to cause breakthrough malaria infection poses formidable safety challenges. To overcome these hurdles, researchers crated genetically attenuated parasites (GAP) by knocking out three genes (GAP3KO) in plasmodium falciparum that arrested its development within the liver, thereby preventing its advance to blood infection, the stage of malaria that triggers disease symptoms.

The GAP3KO vaccine was administrated through infected mosquito bites in a controlled setting. The participants during the human trial, none of whom developed malaria symptoms or signs of infection in the blood, showed strong protective antibody responses, researchers said. When transferred into humanised mice, these antibodies blocked malaria infection in the liver. These promising results pave the way to phase 1b trial of GAP3KO vaccine.

Doctor Sebastian Mikolajczak, Centre for Infectious Disease Research scientist, said, "The clinical study now shows that the GAP3KO vaccine is completely attenuated in humans and also shows that even after only a single administration, it elicits a robust immune response against the malaria parasite

Source: *The Times of India, 6th January 2017*

Vardah Puts off City Lab's Plan to Resume TB Vaccine Production

Cyclone Vardah has dealt a severe blow to the country's universal vaccination programme, setting back the effort to resume manufacture of anti- tuberculosis vaccine for children at city based BCG Vaccine Laboratory by at least five months. The Union health ministry will now have to continue buying these vaccines from private firms at a higher cost.

On Thursday, officials at the laboratory confirmed that mass production of more than 500 doses, scheduled to begin in January won't commence till May.

In October last year, eight years after it was shut for poor manufacturing practices, the laboratory announced it hoped to resume vaccine manufacture by January 2017.

5 MTHS DELAY
FEB 2008 BCG Vaccine Laboratory closed for **not confirming to WHO protocol**

2010 Suspension revoked

2013 City lab begins **construction of new unit**

2016 It gets certification to start trial vaccine production

OCT Lab says it would **resume production by January 2017**

NOV 1st trial **batch harvested**

DEC Power cuts post Vardah and in adequate diesel lead to **temperature variations that affects quality of vaccine**

Lab was shut in 2008

The three days of power cuts they endured podst Vardah, and lack of adequate diesel to run the generators, led to temperature variations that affected the quality of the vaccine, said director H G Brahmne. The Laboratory had just 1200 litres of diesel against the 90 litres per hour required to maintain the temperature. "We make the harvest when the culture is floating, but despite best efforts, the culture sank in the medium because we were not able to keep the vaccine in 37 degree Celsius round the clock,"he said.

In October 2016, eight years after it was shut for poor manufacturing practices, the laboratory said it hoped to resume vaccine manufacture by January 2017. In November, the first official 'trial' batch was harvested and subsequent harvests were of high quality. Scientists decided to start filling vaccines into vials on a trial basis in December. When power was restored after Vardah, the fedding pipe at the refill station had a leak. "We are fixing that as well. We would have sent batches for quality tests and applied for a commercial licence to start production if nothing had gone worng, said Brahmane.

In February 2008, the BCG Vaccine Laboratory, central Research Institute , Kasauli, and Pasteur Institute of India, Coonoor were closed for not confirming to WHO's good manufacturing practices (GMP) protocol. In 2010, the suspension of licences was revoked on the condition that the laboratories put in place WHO-approved GMP. The Chennai lab tried to manufacture vaccines from the old building but failed the quality test. In 2013, it began construction of a new manufacturing unit with GMP protocol. In early 2016, after cenral Drugs Standard Control Organisation certification, trial vaccine production began on September 12.

In November it tested the trial vaccine internally. It planned to send he trial batches to the Central Drugs Laboratory in Kasauli for standard quality certification before applying to the Dr ugs Controller General of India for commercial production licence. In December, the Union health ministry website had notices seeking comments from stakeholders on an amendment of recruitment rules for administrative officer and engineers. A senior official said the government would begin recruiting permanent staff. "We will need manpower to manage the lab and maintain quality.

Source: *The Times of India, 6th January 2017*

Drug Price Regulator Suggests Classifying Stents, Capping Prices

Moving a step closer to capping stent prices, the drug price regulator has proposed classifying the life saving tubes, which keep blood vessels open, under two categories and can offer up to 50% reduction in the cost of drug eluting cardiac stents.

If accepted, the National Pharmaceutical Pricing Authority's (NPPA) proposals will become effective from February. The stents have been primarily placed under to categories – drug eluting stents (DES) and bare metal stents (BMS) with NPPA setting out an option to fix prices.

The options include fixed percentage margins over average price to distributor; hospital, on production cost and on landed cost for imported products. For instance, while most proposed DES ceiling prices are in the range of Rs 20,000- Rs 40,000, the highest at Rs 67,272 has been calculated using the average price of the stent to the hospital topped with a 16% margin. Similarly, another suggestion to fix price of DES at Rs 39,978 is based on average price to the distributor plus a 16% margin.

The pricing decision is now in its final stages with NPPA asking all stakeholders to submit suggestions on the proposed options by January 26. The regulator has also asked companies to submit documents and relevant data to support their representations.

Besides these options, the regulator has also suggested using the current CGHS pricing. Companies provide high quality stents at best prices under the central government health scheme. The maximum retail prices of DES in the market can go up to around Rs 2 lakh, whereas the reimbursement rate for DES under CGHS is Rs 22,500.

NPPA, in its notification dated January 13, has also suggested fixing prices with an annual hike on CGHS price for both DES and BMS categories.

The regulator has proposed that ceiling prices of drug eluting stents, which also include biodegradable stents, be fixed at rates ranging between Rs 10,699 to Rs 67,272. Forbare metal stents, the price ranges between Rs 8,422 to Rs 15,211. In case of bare metal stents, NPPA has differentiated between stainless steel and cobalt stents and accordingly suggested prices caps.
The regulator however, has not accepted suggestions from medical device makers, mainly multinational companies to further differentiate ceiling prices of drug eluting stents based on a matrix that includes criteria like complexity of the stent design or how innovative it is.

Manufacturers have also strongly opposed CGHS as well as distributor price-based mechanisms- which set prices at a lower range. "NPPA is open to consider additional options, if any, which may be suggested by any of the stakeholders," an official said.

Source: *The Times of India, 16th January 2017*

Ebola Vaccine Successful During Human Trials

After years of efforts by the scientific community the world may soon get a vaccine against the deadly Ebola virus. An experimental Ebola vaccine has been found to provide 100 % protection during human trials led by the World Health Organisation.

The findings of the trial conducted in Guinea involving 11,841 people during 2015 – also supports the results of earlier trials that

were published last year.

The vaccine – VSV-ZEBOV – is the first to prevent infection from one of the most known lethal pathogens.

The findings of the latest trial, which were published recently in Lancent show that among the 5837 people who received the vaccine, no Ebola cases were recorded 10 days or more after the vaccination.

Apart from WHO, Guinea's ministry of health, Medecins sans Frontieres and Norwegian Institute of Public Health also participated in the trials."While these compelling results come too late for those who lost their lives during West Africa's Ebola epidemic, they show that when the next Ebola outbreak hits, we will not be defenceless," said Dr Marie Paule Kieny, WHO's assistant director-general for health systems and innovation, and study's lead author.

The vaccine's manufacturer, Merck, Sharpe & Dohme, this year received breakthrough therapy designation from the US Food and Drug Administration and PRIME status from the European Medicines Agency, enabling faster regulatory review of the vaccine once it is submitted.

Since Ebola virus was first identified in 1976, sporadic outbreaks have been reported in Africa. But the 2013-2016 West African Ebola outbreak, which resulted in more than 11,300 deaths, highlighted the need for a vaccine. Though no patient has been detected in India with the virus so far, even a single imported case can create much damage in a densely populated country.

Source: *The Times of India, 24th December 2016*

Zydus Acquires Six MSD Brands

Drug firm Zydus Cadila today said it has acquired six brands from global pharma major MSD and its subsidiaries for an undisclosed amount.

The company's wholly-owned subsidiary Zydus Healthcare Ltd has acquired six brands, which cover various therapeutic areas including wound management, from MSD and its subsidiaries, Zydus Cadila said in a statement.

MSD India is an affiliate of Merck & Co Inc that operates in more than 140 countries around the world.

The acquired brands Deca-Durabolin, Durabolin, Sustanon, Multiload, Sicastat and Axeten range had clocked sales of Rs 840 million in 2015.

The deal includes transfer of distribution and commercialisation rights and assignment of trademarks of all the six brands to Zydus Healthcare Ltd in India, the Ahmedabad-based company said. As a part of the deal, Organon (India) Pvt Ltd, one of the legal subsidiaries through which MSD operates its business in India has also transferred the distribution and commercialisation rights for Deca- Durabolin and Durabolin to Zydus for Nepal, it added. The company however did not disclose financial details. "The brands with their strong equity are a perfect addition and complement our core business and brands. We look at this as a great opportunity to strengthen our core offerings to create value and growth," Zydus Healthcare Chairman Sharvil Patel said.

The brands Deca-Durabolin and Durabolin are amongst the widely prescribed drugs for the treatment of osteoporosis, muscle wasting and management of negative nitrogen balance. Sustanon is the best-known form of injectable testosterone in the men's health segment and is used as a testosterone replacement therapy. Multiload, an IUD device is expected to widen the offerings in women's contraceptives while Axeten is an anti-hypertensive brand. Sicastat is used in wound management.

Source: *Times of India 29th December 2016*

Profits on Stents Range From 270% To 1000%

It is now officially confirmed that a stent can cost the patient over 10 times by the time it moves from the manufacturer to the patient. The National Pharmaceutical Pricing Authority (NPPA) on Monday released data on margins made by players at various levels in the stent trade.

Of all the players, hospital margins appear to be the highest, touching about 650%. Incidentally, along with stent companies, it is hospitals and cardiologists who have been most vocal against price control for stents. Based on data submitted by stent companies, NPPA has worked out the margins at every level and the data shows that the margin on stents range from 270% to about 1000%.

While the biggest jump in price seems to happen at the level of hospitals, not all hospitals might be charging that high a margin as it ranges from 11% to 654%.

The manufacturing cost of a drug eluting stent (DES) for a domestic company is about Rs 8,000 and the price of an imported DES starts at about Rs. 5,000. Combining of the data for DES along with bioabsorbable stents makes it difficult to get an exact idea of just how much the mark-up on DES alone could be. DES constitutes over 95% of the stents used in India.

While the data seems to indicate that the importers or manufacturers charge the lowest margins compared to the margin of distributors (13% to almost 200%) and hospitals, it is well known that many companies operate the markets through their distributors. With most companies claiming to follow ethical codes of marketing, the illegal marketing practices of kickbacks to doctors and hefty cuts to hospitals are left to the dealers or distributors. Hence the margin allowed to dealers ranging from 13% to 196% is said to include the cost of these practices too. In the case of imported stents, there is also the issue of transfer pricing.

With the import being done by the same company, the company could fix whatever price suits it, depending on where it wants to show its profits. Hospital associations, after initially coming out against price control, have since modified their position to say that they are not against price control but are only concerned about the latest innovations in stent technology being available to patients and about the quality of stents.

The official billing prices of stents to hospitals often disguise bigger cuts through a system of distributors giving them a bill showing a higher price. The real price to hospitals is often lower.

Source: *The Times of India, 17th January 2017*

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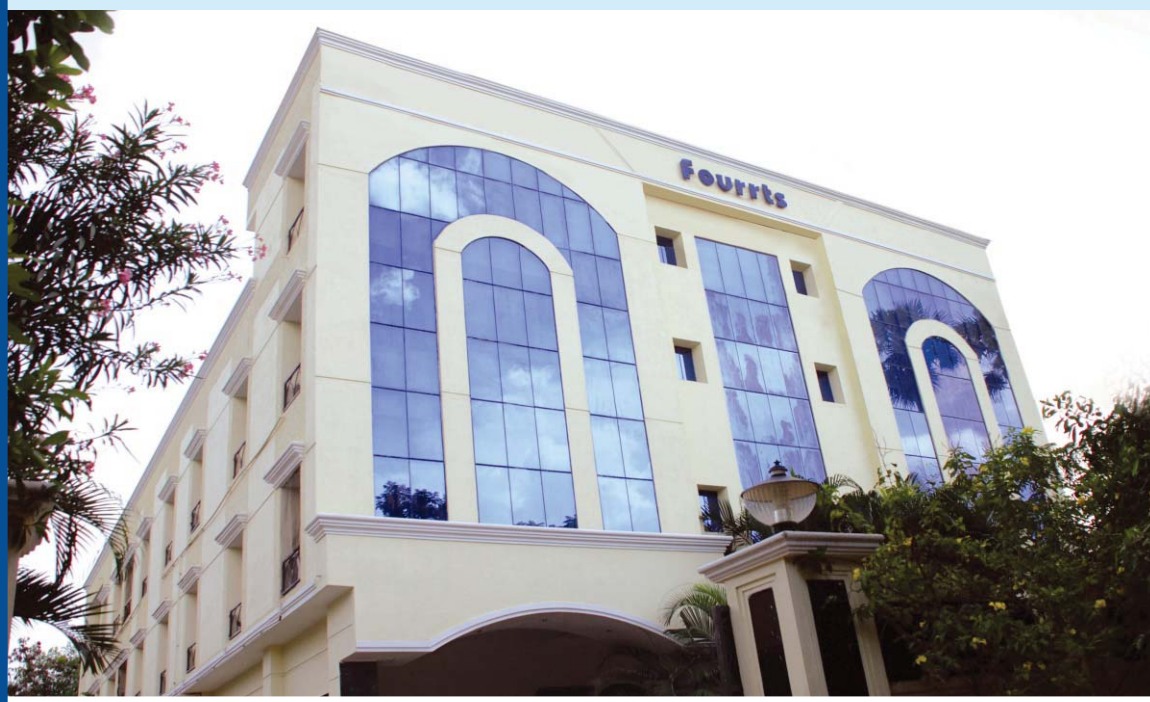

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